UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

In Re CELGENE CORPORATION, INC. SECURITIES LITIGATION

Civil Action No. 18-4772 (MEF) (JBC)

OPINION and ORDER

Table of Contents

I. Background

- A. The Facts
- B. The Lawsuit
- C. Procedural History
- D. The Motion
- E. The Court's Approach
- II. Legal Standards
- III. The Parties' Arguments
- IV. Law of the Case
 - A. The Chief Operating Officer: Statements 1-7
 - B. The Franchise President: Statements 1-4
- V. The Individuals' Scienter
 - A. Introduction
 - <u>1.</u> <u>Law</u>
 - 2. A Complexity
 - 3. The Statements
 - B. A Three-Part Framework for the Analysis
 - C. Part One: Importance to the Company
 - D. Part Two: Importance to the Individuals
 - 1. The Franchise President
 - The Chief Operating Officer
 - E. Part Three: Direct Evidence
 - 1. The Franchise President: Statements 5-7
 - a. The July 25, 2017 Email
 - b. The Briefing Book

2. Statements 8-10

VI. Conclusion

VII. Imputation of Scienter to the Company

- A. Introduction
- B. Law
- C. The Individuals
 - 1. The Chief Operating Officer
 - 2. The Franchise President
 - 3. The Managing Director

VII. Conclusion

* * *

Investors in a pharmaceutical company sued the company and some of its executives.

Their claim: certain public statements indicated the company was close to submitting a new drug application to regulators, even though the application was not well-enough developed; the application was submitted but was bounced back by regulators as incomplete --- and that caused the stock price to fall.

Certain executives and the company moved for summary judgment.

The motion as to the executives was addressed in a prior opinion.

Here, the Court takes up the motion as to the company.

The motion as to the company is granted in part, denied in part, and held in abeyance in part.

I. Background

A. The Facts

The evidence as relevant for now is as follows.

A drug company ("the Company"1) spent a number of years

¹ The Company is Celgene Corporation, Inc. <u>See</u> Third Amended Consolidated Class Action Complaint (the "Complaint") at 1, \P 41.

developing a particular drug (the "Drug"²). <u>See</u> Defendants' Statement of Material Facts Not in Dispute Pursuant to Local Civil Rule 56.1 ("Defendants' Rule 56 Statement") ¶¶ 3-4.

As part of doing so, the Company assessed the metabolites, if any, that use of the Drug might generate. See id. at ¶¶ 12-13.

Metabolites are "the chemical byproducts of the body breaking down a drug." $\underline{\text{Id}}$. at ¶ 12. The Food and Drug Administration ("FDA") considers "whether any major metabolites exist, and if so, whether they affect the safety or efficacy of a proposed drug," when it decides whether to approve a new drug. $\underline{\text{See}}$ $\underline{\text{id}}$. at ¶ 22.

* * *

During 2017, two sets of things happened.

First, during the initial months of the year, certain Company employees began to zero in on the possibility that the Drug potentially produced a particular metabolite ("Metabolite"). And by June, the Metabolite's existence was said to have been "definitively confirmed."

Second, the Company put out a series of public statements, describing the Drug application it was gearing up to submit to the FDA. See Complaint ¶¶ 397-399, 403, 405-408, 411; cf. id. at ¶¶ 420, 422, 424; see also Defendants' Rule 56 Statement ¶¶ 37-38, 41, 43-44, 56. The gist of the statements: the Company would soon apply for FDA approval to market the Drug. See Complaint $\P\P$ 397-399, 403, 405-408, 411; cf. id. at $\P\P$ 420, 422,

 $^{^2}$ The Drug is Ozanimod. See Complaint \P 10.

³ See Declaration of James E. Cecchi in Support of Lead Plaintiff's Response Pursuant to Local Civil Rule 56.1 to Defendants' Statement of Material Facts Not in Dispute and Lead Plaintiff's Supplemental Statement of Disputed Material Facts Pursuant to Local Civil Rule 56.1 (the "Cecchi Declaration"), Ex. 18 at CELG-AMF 00967643 (January 2017 meeting minutes from the "[Drug] Team"); Cecchi Declaration, Ex. 21 at CELG-AMF 01229070 ("[Drug] Stakeholders" "NDA Submission Dashboard for the week of Mar 27th [2017]").

^{4 &}lt;u>See</u> Declaration of Nidhi Yadava in Support of Defendants' Motion for Partial Summary Judgment (the "Yadava Declaration"), Ex. 21 at CELG-AMF 01303197 (June 22, 2017 email to key members of the Company's Drug development team: "We have definitively confirmed [a metabolite] as the peak in human plasma.").

424; see also Defendants' Rule 56 Statement $\P\P$ 37-38, 41, 43-44, 56.

* * *

The Company filed the application at the end of 2017, but it was sent back by the FDA a couple of months later, in February of 2018. See Defendants' Rule 56 Statement ¶¶ 62, 66-69.6

Per the FDA: the application was too sparse. It did not lay out enough information as to Metabolite-related studies and what they had shown. See Cecchi Declaration, Ex. 78 at CELG-AMF 01420920-23.

After the FDA's decision, the Company's stock price fell by around 8.5%. See Lead Plaintiff's Supplemental Statement of Disputed Material Facts Pursuant to Local Civil Rule 56.1 (the "Plaintiffs' Rule 56 Statement") ¶ 117; Memorandum of Law in Support of Defendants' Motion for Partial Summary Judgment (the "Motion for Summary Judgment") at 13.

B. The Lawsuit

Emphasizing alleged daylight between external statements (the application is coming) and internal information (it might not be far enough along), some investors sued in 2018 on behalf of a putative class of Company stockholders. See Complaint $\P\P$ 22-35, 473.

From here, these investors are referred to as "the Plaintiffs." The Plaintiffs sued under the Securities Exchange Act of 1934 (the "Act"). See id. at ¶¶ 36, 488-492.

The lawsuit is in one count, based on Section 10(b) of the Act and Rule 10b-5.7 See id. at ¶¶ 488-489.

The application was a New Drug Application. See generally In re Suboxone (Buprenorphine Hydrochlorine & Naloxone) Antitrust Litig., 967 F.3d 264, 267 (3d Cir. 2020) (describing the New Drug Application process).

The FDA issued a Refusal to File. See Defendants' Rule 56 Statement ¶ 66. A Refusal to File cuts things off at the pass. It is "a regulatory decision from the FDA denying the complete review of a[] [New Drug Application]." Defendants' Rule 56 Statement ¶ 15; see generally 21 C.F.R. § 314.101(d).

^{7 &}quot;Rule 10b-5 implements section 10(b) of the Securities Exchange Act." Riley v. Simmons, 45 F.3d 764, 773 n.9 (3d Cir.

C. Procedural History

The suit moved forward. A class was certified, see Order (November 29, 2020), discovery got underway and wrapped up, and during the fall of 2023, the Court, per Judge Vazquez, ruled on the Defendants' summary judgment motion, granting it in part and denying it in part. See Order (September 8, 2023). Judge Vazquez indicated that part of the denial was without prejudice --- that is, a part of the summary judgment motion could be later renewed. See id. at 2.

Judge Vazquez retired, and the case was definitively reassigned to the undersigned in January of 2024.

D. The Motion

The Company⁸ and certain Company employees⁹ have renewed their summary judgment motion. (The Company and the Company employees are referred to here, collectively, as "the Defendants.")

Oral argument was held, and the summary judgment motion was resolved as to one of the Defendants around five weeks ago. See In re Celgene Corp., Inc. Sec. Litig., 2024 WL 3503486, at *1 (D.N.J. July 23, 2024).

In light of the decision, the United States Magistrate Judge convened the parties to explore the possibility of settlement. The parties wrote to the Court a few weeks ago, indicating that there was no settlement and that the summary judgment motion as to the Company should therefore be decided.

The Court takes up the motion here.

E. The Court's Approach

To analyze the motion, the Court first lays out the governing securities law principles. <u>See</u> Part II. These are grounded on one core idea: to hold a corporation liable under 10b-5, as the Plaintiffs seek to do here, it must be established, among other things, that: (a) a person had a mental state of scienter, and

^{1995);} see also Globis Cap. Partners, L.P. v. Stonepath Grp., Inc., 241 F. App'x 832, 835 (3d Cir. 2007) (the Act's "[S]ection 10(b) . . . is enforced through Rule 10b-5").

⁸ Recall: Celquee Corporation, Inc. See footnote 1.

 $^{^9}$ Scott Smith, Terrie Curran, and Philippe Martin. Each is a named defendant. See Complaint ¶¶ 43-45.

(b) that person's mental state can be imputed to the corporation.

Next, the Court briefly canvasses the parties' arguments, <u>see</u> Part III, establishing that the Plaintiffs' claims are based on liability running to the Company from three particular Company employees and based on ten particular Company statements.

But the Court concludes that part of the Plaintiffs' argument cannot now work --- because of prior decisions the Court has made, and the credit that is due to them under the law of the case doctrine. See Part IV.

As to the arguments that are left, the Court's analysis is in two parts.

In Part V, the Court analyzes whether a reasonable jury could conclude that two of the three Company employees had scienter with respect to the Company statements. The Court's conclusion: yes, as to certain pairings of employees and statements.

As to those pairings, the Court considers, <u>see</u> Part VII, whether the employees' scienter can be imputed to the Company. The Court's conclusion: yes. (As to the third Company employee, the Court concludes that he did not have scienter, and that even if he did it could not be imputed. See id.)

II. Legal Standards

Start the analysis with the general legal standards that are in play here. 10

Beyond those set out in the text, other general standards matter here, too. These include the principles that govern a summary judgment motion. Such a motion should be granted if "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); see also Dupree v. Younger, 598 U.S. 729, 737 (2023); Cellco P'ship v. White Deer Twp. Zoning Hearing Bd., 74 F.4th 96, 100 (3d Cir. 2023). "A factual dispute is material if it might affect the outcome of the suit under the governing law." Canada v. Samuel Grossi & Sons, Inc., 49 F.4th 340, 345 (3d Cir. 2022) (cleaned up); see also Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). Such a dispute is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party[.]" SodexoMAGIC, LLC v. Drexel Univ., 24 F.4th 183, 203-04 (3d Cir. 2022). In assessing a summary judgment motion, "a district court may not make credibility determinations or engage in any weighing of the evidence[.]" Marino v. Indus. Crating Co., 358

As noted, <u>see</u> Part I.B, the Plaintiffs sued under Section 10(b) of the Securities Exchange Act of 1934, as implemented by Rule 10b-5.

To prove a 10b-5 claim, the Plaintiffs must establish "six elements: (i) a misrepresentation or omission of material fact; (ii) scienter; (iii) a connection with the purchase or sale of a security; (iv) reliance; (v) economic loss; and (vi) loss causation." City of Warren Police & Fire Ret. Sys. v. Prudential Fin., Inc., 70 F.4th 668, 679 (3d Cir. 2023).

The Defendants have moved for summary judgment as to the Company on one argument: that the Company did not have scienter. See Motion for Summary Judgment at 15-25.11

The Defendants' motion runs through a seeming-contradiction in the law.

On the one hand: a company can be liable under the Securities Exchange Act of $1934,^{12}$ and for it to be liable it must have scienter. 13

On the other hand: scienter is "a mental state," Ernst & Ernst, 425 U.S. at 193 n.12 (cleaned up), and a company cannot have a mental state in a traditional sense, because it does not have a mind. See Smallen v. The W. Union Co., 950 F.3d 1297, 1312 (10th Cir. 2020); Thompson v. RelationServe Media, Inc., 610 F.3d 628, 635 (11th Cir. 2010); Mizzaro v. Home Depot, Inc., 544 F.3d 1230, 1254 (11th Cir. 2008).

F.3d 241, 247 (3d Cir. 2004). Rather, the court must "view the facts in the light most favorable to the non-moving party and draw all reasonable inferences in that party's favor." <u>Canada</u>, 49 F.4th at 345 (cleaned up); <u>accord Tolan v. Cotton</u>, 572 U.S. 650, 660 (2014).

Scienter is an "intent to deceive, manipulate, or defraud." Ernst & Ernst v. Hochfelder, 425 U.S. 185, 193 n.12 (1976).

Compare 15 U.S.C. § 78c(a)(9) (including "company" as part of the definition of "person") with 15 U.S.C. § 78j(b) (making it unlawful for "any person" to use manipulation or deception in connection with the sale of a security).

See Ernst & Ernst, 425 U.S. at 201; <u>Tellabs, Inc.</u> v. <u>Makor Issues & Rts.</u>, Ltd., 551 U.S. 308, 319 (2007).

But cf. Makor Issues & Rts., Ltd. v. Tellabs Inc., 513 F.3d 702, 707 (7th Cir. 2008) (suggesting that a corporation can have a "collective intent" or "shared purpose"); Jackson v. Abernathy, 960 F.3d 94, 98 (2d Cir. 2020) (similar).

These propositions pull in different directions. A company can be liable. But it can be liable only if it has scienter --- which companies cannot themselves have.

How to square the circle? In two steps. First, courts typically ask whether a particular person has scienter. second, courts typically ask whether that person's scienter should be imputed to the company. See Jackson, 960 F.3d at 98; Smallen, 950 F.3d at 1312; Southland Sec. Corp. v. INSpire Ins. Sols., Inc., 365 F.3d 353, 366 (5th Cir. 2004); Bondali v. Yum! Brands, Inc., 620 F. App'x 483, 493 (6th Cir. 2015); Yoshikawa v. Exxon Mobil Corp., 2022 WL 4677621, at *9 (N.D. Tex. Sept. 29, 2022); In re Skechers USA, Inc. Sec. Litig., 444 F. Supp. 3d 498, 529 (S.D.N.Y. 2020); In re Monster Worldwide, Inc. Sec. Litig., 549 F. Supp. 2d 578, 583 (S.D.N.Y. 2008); In re Hutchinson Tech. Inc. Sec. Litig., 502 F. Supp. 2d 884, 902 (D. Minn. 2007), aff'd sub nom., In re Hutchinson Tech., Inc. Sec. Litig., 536 F.3d 952 (8th Cir. 2008); In re Marsh & Mclennan Companies, Inc. Sec. Litig., 501 F. Supp. 2d 452, 481 (S.D.N.Y. 2006); In re BISYS Sec. Litig., 397 F. Supp. 2d 430, 442-43 (S.D.N.Y. 2005); In re Alamosa Holdings, Inc., 382 F. Supp. 2d 832, 858 (N.D. Tex. 2005); Piper Jaffray Cos. Inc. v. Nat'l Union Fire Ins. Co. of Pittsburgh, 38 F. Supp. 2d 771, 779 (D. Minn. 1999); see also City of Roseville Emps. Ret. Sys. v. Horizon Lines, Inc., 442 F. App'x 672, 676 (3d Cir. 2011). 15

¹⁵ There may be other ways to think about corporate scienter. For example, collective knowledge doctrines have long been used in certain areas of the law, like search and seizure. generally, e.g., United States v. Hensley, 469 U.S. 221 (1985); Whiteley v. Warden, Wyo. State Penitentiary, 401 U.S. 560 (1971). Those sorts of doctrines look to whether the shared knowledge of multiple people adds up to enough --- rather than to whether the knowledge of one person is enough. In the securities context, courts have sometimes suggested that the collective knowledge approach is flawed, in part, because it lacks a limiting principle --- it could allow for aggregating the knowledge of people who work separately, in different corners of a far-flung enterprise and unknown to each other. Judge Posner, for example, has made this point. See Makor, 513 F.3d at 707-08. But it may be possible to address this concern by limiting the set of people whose knowledge can be aggregated. In the search and seizure context, for example, the focus is generally (though not always) on the collective knowledge of only those people who were directly involved in making the challenged decision. See, e.g., United States v. Woods, 544 F.2d 242, 260 (6th Cir. $\overline{1976}$) ("[W]hen a group of agents in

III. The Parties' Arguments

The Plaintiffs make use of the two-part bank-shot argument set out just above.

They contend the Company is liable for ten specific statements, see Memorandum in Opposition at 12-25; Complaint ¶¶ 397, 398-399, 403, 405, 406, 407-408, 411, 420, 422, 424, 489, 491, based on the scienter of each of three people. These people were Company employees: Scott Smith, Terrie Curran, and Phillippe Martin. See Memorandum in Opposition at 12-25; Plaintiffs' Letter (May 24, 2024) at 2-5. Smith had scienter and that can be imputed to the Company; Curran had scienter and that can be charged to the Company; and Martin had scienter and that can be charged to the Company. See id. at 2-5; Memorandum in Opposition at 12-25.

For their part, the Defendants disagree at both steps of the argument.

They contend: as to the ten relevant statements, none of the three individuals had scienter --- and for anyone who did, their scienter cannot be charged to the Company. See Motion for

close communication with one another determines that it is proper to arrest an individual, the knowledge of the group that made the decision may be considered in determining probable cause, not just the knowledge of the individual officer who physically effected the arrest."). Other collective knowledge contexts build in analogous limits. See generally United States v. Avellino, 136 F.3d 249, 255-56 (2d Cir. 1998) (describing limits on whose knowledge counts as the prosecutor's for Brady purposes). In the '34 Act context, the same approach could potentially be taken --- with a focus on those directly involved in the specific corporate act that has been challenged. example, if the challenged corporate act is making a misleading statement in a 10-K, then the focus might be on the collective knowledge of the people who directly prepared and vetted the If the concern is possible liability when "the right hand does not know what the left hand is doing," Ann M. Lipton, Slouching Towards Monell: The Disappearance of Vicarious Liability Under Section 10(B), 92 Wash. U. L. Rev. 1261, 1270 (2015), that should be less of an issue when right and left are in fact working together, on a shared and bounded task. this, though, is for another day --- neither party suggests an approach here other than the one set out in the text. generally Wu v. GSX Techedu Inc., 2024 WL 3163219, at *25 (D.N.J. June 25, 2024) (discussing the party-presentation principle).

Summary Judgment at 15-25; Reply in Support of Defendants' Motion for Partial Summary Judgment ("Reply Brief") at 2-15. 16 This is where and when the ten statements were made:

Statement	Where	When	Source
1	Company 10-Q	July 27, 2017	Complaint ¶ 397
2	Conference Call	July 27, 2017	Complaint ¶ 398-399
3	Company 8-K	July 27, 2017	Complaint ¶ 403
4	Conference Presentation	September 26, 2017	Complaint ¶ 405
5	Company 10-Q	October 26, 2017	Complaint ¶ 406
6	Conference Call	October 26, 2017	Complaint ¶ 407
7	Press Release	October 26, 2017	Complaint ¶ 411
8	Press Release	January 8, 2018	Complaint ¶ 420
9	Company 8-K	January 25, 2018	Complaint ¶ 422
10	Company 10-K	February 7, 2018	Complaint ¶ 424

¹⁶ The Defendants also make another argument. They say that under the Supreme Court's decision in Janus Cap. Grp., Inc. v. First Derivative Traders, 564 U.S. 135, 141 (2011), a person must be a statement-maker for their scienter to be imputed to a corporation. See Motion for Summary Judgment at 16-19; Opposition Brief at 22-25; Reply Brief at 3-7. Not so. neither says nor implies anything along these lines. Indeed, it does not purport to address scienter. And "many courts that have considered the issue since Janus have applied . . . longstanding imputation principles." Sec. & Exch. Comm'n v. City of Victorville, 2018 WL 3201676, at *3 (C.D. Cal. Jan. 24, 2018) at *3; cf. Patel v. L-3 Commc'ns Holdings Inc., 2016 WL 1629325, at *15 n.38 (S.D.N.Y. Apr. 21, 2016) ("The person whose state of mind is imputed to the company need not also be the person who made the material misstatements at issue."); Pa. Pub. Sch. Employees' Ret. Sys. v. Bank of Am. Corp., 874 F. Supp. 2d 341, 372 (S.D.N.Y. 2012) (no requirement "that an individual whose knowledge is imputed to the corporation must also make the material misstatement or omission at issue") (cleaned up).

As noted, the Plaintiffs argue that the Company can be liable for these ten statements based on the mental state (scienter) of each of three Company employees or former employees --- Scott Smith, Terrie Curran, and Philippe Martin.

This adds up to 30 total ways for the Company to be potentially liable, as this chart shows:

Statement	When	Smith	Curran	Martin
1	July 27, 2017			
2	July 27, 2017			
3	July 27, 2017			
4	September 26, 2017			
5	October 26, 2017			
6	October 26, 2017			
7	October 26, 2017			
8	January 8, 2018			
9	January 25, 2018			
10	February 7, 2018			

Before going forward, a note: from here the three above-listed people are referred to by the Company titles they held at relevant points.

Scott Smith is called "the Chief Operating Officer."

Terrie Curran was the chief of the Company division --- called a "Franchise" --- responsible for the Drug. She is "the Franchise President."

And Philippe Martin was the Managing Director of the Company location that worked heavily on developing the Drug. He is the "Managing Director."

IV. Law of the Case

In this Part, the Court explains the implications of the "law of the case" doctrine, and reaches two conclusions.

First, there is no scienter here as to the Chief Operating Officer on statements 1 through 7 --- Judge Vazquez previously so held. See Part IV.A.

And <u>second</u>, there is no scienter here as to the Franchise President on statements 1 through 4 --- because that is the implication of the "rule of law" that Judge Vazquez laid down as to the Chief Operating Officer.

Accordingly, scienter cannot be imputed to the Company for statements 1 through 7 based on the mental state of the Chief Operating Officer, and scienter cannot be imputed to the Company for statements 1 through 4 based on the mental state of the Franchise President.

* * *

A note at the outset: the law of the case doctrine is operative here.

<u>First</u>, the parties occasionally invoke the doctrine by name. See, e.g., Defendants' Letter (May 24, 2024) at 2.

Second, they make references throughout their papers to the implications of the Court's prior rulings. See, e.g., Motion for Summary Judgment at 2-3, 19, 23-25; Memorandum in Opposition at 2, 19-20. This, too, counts as calling upon the law of the case doctrine. See United States ex rel. Petratos v. Genentech Inc., 855 F.3d 481, 493 (3d Cir. 2017).

And third, a court may raise the law of the case doctrine on its own. See Brigham & Women's Hosp., Inc. v. Perrigo Co., 761 F. App'x 995, 1002 (Fed. Cir. 2019); United States v. Anderson, 772 F.3d 662, 669 (11th Cir. 2014); United States v. Matthews, 643 F.3d 9, 12 n.2 (1st Cir. 2011); Maxfield v. Cintas Corp., No. 2, 487 F.3d 1132, 1135 (8th Cir. 2007); DiLaura v. Power Auth. of State of N.Y., 982 F.2d 73, 76 (2d Cir. 1992). The Court does so here. 17

The Third Circuit does not seem to have weighed in on whether the law of the case doctrine can be raised <u>sua sponte</u>. So a brief word as to one of the reasons why doing so is appropriate. A basic division of labor in our legal system is that the parties pick the arguments they want to make, <u>see</u>, <u>e.g.</u>, <u>Greenlaw v. United States</u>, 554 U.S. 237, 244 (2008), but when it comes to evaluating those arguments --- it is for the Court to then "say what the law is." <u>Marbury v. Madison</u>, 5 U.S. 137, 177 (1803). The law of the case doctrine is directed at the court, and its basic job is to indicate for the court "what the law is." What is the law? The law of the case doctrine answers: the law includes those rules that were previously laid down in the course of the case. (In a sense, the law of the case doctrine is a kind of small-bore "rule of recognition." See

A. The Chief Operating Officer: Statements 1-7

Consider, first, the Plaintiffs' argument --- pressed here only lightly --- that the Chief Operating Officer's scienter as to statements 1 through 7 can be charged to the Company. <u>See</u> Part III.

The problem with this argument: Judge Vazquez previously held that the Chief Operating Officer did not have scienter through October 2017, and that includes the period when statements 1 through 7 were made. See Argument Transcript (Sept. 7, 2023) at 102:4-19, 102:25-106:4, 108:11-18; Order (May 8, 2023) at 1.

Judge Vazquez's ruling is subject to the law of the case doctrine, as noted above.

Under that doctrine, "when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case." <u>Arizona</u> v. <u>California</u>, 460 U.S. 605, 618 (1983).

This is a discretionary rule, not a mandatory one. A court at Time 2 "should" hew to its decision at Time 1. But it does not have to. 18

generally H.L.A. Hart, The Concept of Law 90-99 (2d ed. 1994). The law of the case doctrine does not fold a new argument into the mix, any more than a new argument is added in when the court follows other, similar doctrines that are directed at it --like the doctrine to hew to the prior decisions of a superior court, or the doctrine to start with the text of a federal statute. The court follows precedent, and it looks to the statutory text --- even if a party does not make any specific arguments along those lines. The court does so because it has its own obligation to say what counts as the law. The law of the case doctrine does similar work. It points out where to find the law; prior decisions in a case are a place to find the law, just as precedent and a statute's text are places to find the law. All of these (following the law of the case or hewing to precedent or reading the statute's text) can be done sua sponte --- because they are not about taking a position (that is for the parties), they are about saying what the law is (and that is for the court).

This was the old federal common law rule. See, e.g., Remington v. Cent. Pac. R. Co., 198 U.S. 95, 100 (1905); accord, e.g., S. Ry. Co. v. Clift, 260 U.S. 316, 319 (1922); King v. State of W. Virginia, 216 U.S. 92, 100 (1910). And discretion has been re-confirmed --- in Federal Rule of Civil Procedure 54(b), and in the modern cases. See, e.g., Christianson v. Colt

Here, the Court does not exercise its discretion to depart from Judge Vazquez's prior ruling, for three reasons.

 $\underline{\text{First}}$, no one has directly asked the Court to do so. $\underline{\text{See}}$ $\underline{\text{Greenlaw}}$, 554 U.S. at 244 ("as a general rule, our adversary system is designed around the premise that the parties know what is best for them, and are responsible for advancing the facts and arguments entitling them to relief") (cleaned up).

And this silence is especially telling. Judge Vazquez's ruling on the Chief Operating Officer's scienter has not been obscure. It was, for example, discussed at oral argument before the undersigned. See Argument Transcript (May 15, 2024) at 6:23-7:25, 32:5-11, 51:1-17, 59:1-12, 60:8-20.

And in addition, in their initial round of post-argument briefing, the Defendants treated the question of the Chief Operating Officer's scienter through October 2017 as a closed issue, one that had been resolved. See Defendants' Letter (May 24, 2024) at 3. The Plaintiffs' response did not object to this way of thinking. See Plaintiffs' Letter (May 31, 2024) at 2; Plaintiffs' Letter (May 24, 2024).

<u>Second</u>, one of the bases of the law of the case doctrine is to "promot[e] the finality and efficiency of the judicial process by protecting against the agitation of settled issues." Christianson, 486 U.S. at 816 (cleaned up).

That rationale applies here.

Time was invested, attention was focused, and a decision was made. As to the Chief Operating Officer, the issue at hand has been reached and resolved, and is in the rear-view mirror. Undoing that resolution does not make sense from the perspective of "finality and efficiency." Id. And there is no changed circumstance to point to. There is no new evidence, for example, and no change in the law. See generally Pub. Int. Rsch. Grp. of New Jersey, Inc. v. Magnesium Elektron, Inc., 123 F.3d 111, 116-17 (3d Cir. 1997).

<u>Third</u> and finally, the Court's view is that Judge Vazquez's ruling was right on the merits --- taking into account the dollop of law of the case deference that is due to it, 19 and even without that extra thumb on the scale.

<u>Industries Operating Corp.</u>, 486 U.S. 800, 815 (1988); <u>Arizona</u>, 460 U.S. at 618-19.

That deference has been invoked in law of the case contexts under slightly different verbal formulations. See, e.g., Christianson, 486 U.S. at 817 ("courts should be loathe" to

Better, though, to take this point up a bit later, as the merits come into view. See Part V.E.1.

B. The Franchise President: Statements 1-4

Turn now to the law of the case doctrine as it concerns the scienter of the Franchise President as to statements 1 through 4.

* * *

Before getting there, a brief note.

The Defendants suggest that the Franchise President's scienter (to the extent there is scienter) is out of bounds here --- and therefore cannot potentially be charged to the Company. See Defendants' Letter (May 24, 2024) at 2. The reason why: the Defendants say the Plaintiffs abandoned any such imputation argument. See id.

But the Plaintiffs' opening brief repeatedly invited the Court to make a Franchise-President-to-the-Company scienter inference. See, e.g., Memorandum in Opposition at 8, 10, 13, 15, 16 n.3. The issue was there on the face of the Plaintiffs' papers, which is why the Court honed-in on it at oral argument.

To be sure, this case is a sprawling one, and it has any number of nooks and crannies. Accordingly, after oral argument the Court invited the parties to provide additional briefing and evidence on the issue of the Franchise President's scienter. See Argument Transcript (May 15, 2024) at 61:16-64:2. Multiple

depart from prior decisions); Fagan v. City of Vineland, 22 F.3d 1283, 1290 (3d Cir. 1994) ("a successor judge should not lightly overturn decisions of his predecessors in a given case"); Hayman Cash Reg. Co. v. Sarokin, 669 F.2d 162, 165 (3d Cir. 1982) (if the law of the case doctrine applied, "Judge Sarokin should have deferred to Judge Richey's [prior] decision"); cf. Aleynikov v. Goldman Sachs Grp., Inc., 2022 WL 421398, at *3 (3d Cir. Feb. 11, 2022) ("in determining whether to depart from the law of the case doctrine . . . we owe our earlier panel a certain degree of deference since it has already ruled on the issue at hand") (cleaned up). At least some deference to the court's earlier decision would seem to be logically necessary. Otherwise, the law of the case doctrine would do no practical work. It would carry no consequences. Rather, it would just be a label for prior court rulings. Cf. Muhammad v. State Farm Indem. Co., 2024 WL 833554, at *10 (D.N.J. Feb. 28, 2024) (arguing that Time 2 to Time 1 deference is logically compelled, in an arguably analogous context).

submissions on this issue were then made. <u>See</u> Docket Entries 295-296 & 300-301.

This matters here because one reason for the abandonment doctrine that the Defendants invoke, <u>see</u> Defendants' Letter (May 24, 2024) at 2, is to prevent unfairness --- a party cannot be expected to take on an argument it does not think is still in the mix, because it believes the other party has walked away from it.

But any possible unfairness here has been dissipated by the invitation to file supplemental briefs. Cf., e.g., Kengerski v. Harper, 6 F.4th 531, 538 (3d Cir. 2021) (considering an argument, not initially raised by the relevant party, because the other party had an opportunity to address the issue); United States v. Boggi, 74 F.3d 470, 478 (3d Cir. 1996) (stating that ordinarily courts do not consider arguments raised for the first time in reply briefs so the opposing party is "not prejudiced by the lack of an opportunity to respond to issues raised for the first time in an appellant's reply brief," but considering such an argument because both sides were allowed to address it); Bayer AG v. Schein Pharm., Inc., 129 F. Supp. 2d 705, 716 (D.N.J. 2001), aff'd sub nom., Bayer AG v. Schein Pharms., Inc., 301 F.3d 1306 (Fed. Cir. 2002).

* * *

Look now to the impact here of the law of the case doctrine on the question of the scienter as to statements 1 through 4 of the Franchise President.

Earlier, the Court skipped over the substantive basis of Judge Vazquez's ruling that the Chief Operating Officer did not have scienter through early October 2017, and therefore did not have scienter for statements 1 through 7. See Argument Transcript (Sept. 7, 2023) at 102:4-19, 102:25-106:4, 108:11-18; Order (May 8, 2023) at 1.

For now, note only that the basis of Judge Vazquez's ruling was that as of October 2017 there was only one relevant piece of scienter evidence. Namely, the Chief Operating Officer had been told by email about the Metabolite --- but was also told in the same email that the discovery of the Metabolite would not pose a problem. See Argument Transcript (Sept. 7, 2023) at 102:20-104:11.

This "rule of law" covers "the same issue[]" as it crops up as to the Franchise President. Arizona, 460 U.S. at 618.

As of the time when statements 1 through 4 were made, the evidence is that the Franchise President was in the same boat as

the Chief Operating Officer. She received the same email as the Chief Operating Officer --- the one that mentioned the Metabolite, but in the same breath said the Metabolite would not be a concern. See Cecchi Declaration, Ex. 3 at CELG-AMF 01030045. And, for that point in time, there is no further evidence as to the Franchise President's scienter.

This suggests that the Franchise President, like the Chief Operating Officer, had no scienter for statements 1 through 4 for the same reason, Judge Vazquez held, the Chief Operating Officer did not have scienter for statements 1 through 7.

The Plaintiffs do not argue that the "rule of law" laid down as to the Chief Operating Officer should not apply to the Franchise President. 20

If anything, the opposite. The Plaintiffs try to distinguish Judge Vazguez's Chief Operating Officer holding. See Plaintiffs' Letter (May 24, 2024) at 2-3, 5; Plaintiffs' Letter (May 31, 2024) at 2. But they do not imply that Judge Vazquez's holding is anything other than a fixed point, from which to reason to a conclusion about the Franchise President. makes sense. A core goal of the law of the case doctrine is to ensure consistency. See, e.g., United States ex rel. Petratos v. Genentech Inc., 855 F.3d 481, 493 (3d Cir. 2017); see also Hamilton v. Leavy, 322 F.3d 776, 787 (3d Cir. 2003); cf. In re City of Philadelphia Litig., 158 F.3d 711, 718 (3d Cir. 1998) (invoking "jurisprudential integrity"). That goal would be thwarted if the logic that held sway earlier in a case is jettisoned later --- just because it is being applied to someone In a one-party-on-each-side case, the law of the case doctrine mainly serves one rule of law value --- imposing a kind of finality on the back-end, both to ensure that strong arguments are made on the front-end and for the sake of overall efficiency. See Christianson, 486 U.S. at 816. In a multidefendant case postured like this one, there is, if anything, an added rule of law value in play --- the need to treat like cases The Chief Operating Officer and the Franchise President are similarly situated. The rule that was formulated and then applied to one should be applied to the other, even if it is to be applied a bit later in the litigation. (To be sure, there are sometimes problems with applying the "rule of law" from Time 1 to a different party at Time 2. The second party, for example, may not have been in the case at Time 1, and therefore had no realistic way to follow the proceedings and weigh in. See, e.g., Hamilton, 322 F.3d at 787. In that context, the first ruling may be credited only as a matter of horizontal stare decisis --- not in the somewhat stronger way imagined by

Rather, they seek only to distinguish the Franchise President from the Chief Operating Officer. But their proposed distinctions do not work.

First, the Plaintiffs say that the Franchise President had scienter based on her receipt of a July 2017 email, that told her about the Metabolite. See Plaintiffs' Letter (May 24, 2024) at 2. But this is a point of similarity with the Chief Operating Officer, not difference. He received the same email, and on the same day. See Cecchi Declaration, Ex. 3 at CELG-AMF 01030045.

And <u>second</u>, the Plaintiffs point to a separate July 2017 email from a Company employee working on the Drug application. <u>See</u> Plaintiffs' Letter (May 24, 2024) at 2. (The Franchise President is not on the email.)

With the benefit of a hard squint, the email can perhaps be read to suggest that the sender of the email had spoken to the Franchise President --- and told her that, because of the discovery of the Metabolite, there might be difficulties down the road. See Cecchi Declaration, Ex. 117 at CELG-AMF 04746683.

Is that the right reading of the email? Maybe, maybe not.

But if it is --- then the email suggests the Chief Operating Officer was told a closely similar thing. <u>See id</u>. ("[the Franchise President] was informed yesterday evening by [the Managing Director] and I understand that . . . [the Chief Operating Officer] ha[s] been informed").

And Judge Vazquez had this email in front of him when he ruled. See Declaration of James E. Cecchi (Filed July 5, 2023), Ex. 223 at CELG-AMF 04746683; Lead Plaintiff's Memorandum of Law in Opposition to Defendants' Motion for Summary Judgment (Filed July 5, 2023) at 37-38. Indeed, Judge Vazquez seems to have specifically invoked the email in laying out his reasoning as to the Chief Operating Officer. See Argument Transcript (Sept. 7, 2023) at 103:17-21.

The same information that, per Judge Vazquez, was not enough to establish scienter as to the Chief Operating Officer cannot,

the law of the case doctrine. See In re Staff Mortg. & Inv. Corp., 625 F.2d 281, 282-283 (9th Cir. 1980), superseded by statute on alternative grounds; accord Hamilton, 322 F.3d at 787 ("highly persuasive authority") (cleaned up). But none of this is a live concern here, and no one argues that it is.)

now, be treated as a basis for distinguishing the Franchise President --- and, as to her, coming to the opposite conclusion.

In short, the Plaintiffs' proposed distinctions between the Chief Operating Officer and the Franchise President are not persuasive, and the Franchise President lacks scienter as to statements 1 through 4 --- under the same "rule of the law" that was previously applied to the Chief Operating Officer.²¹

* * *

The chart below reflects where things stand.

For statements 1 through 7, the Company's scienter cannot potentially be predicated on the Chief Operating Officer's scienter --- because Judge Vazquez held the Chief Operating Officer did not have scienter for those statements.

And for statements 1 through 4, the Company's scienter cannot potentially be based on the Franchise President's. The logic of Judge Vazquez's Chief Operating Officer holding is that the Franchise President did not have scienter during the period covered by statements 1 through 4.

Statement	When	Smith	Curran	Martin
1	July 27, 2017	X	X	
2	July 27, 2017	Х	X	
3	July 27, 2017	X	X	
4	September 26, 2017	Х	X	
5	October 26, 2017	X		
6	October 26, 2017	Х		
7	October 26, 2017	Χ		
8	January 8, 2018			
9	January 25, 2018			
10	February 7, 2018			

In addition, the Court's conclusion on the merits is that the Franchise President did not have scienter --- and again, even putting aside the deference that Judge Vazquez's prior ruling is due. The merits analysis is below, in Part V.E.1.

V. The Individuals' Scienter

A look at the above chart shows 19 empty boxes. Each represents a still-remaining way that the Plaintiffs might be able to hold the Company liable as to a given statement. The Defendants argue that summary judgment must be granted because none of these work --- (a) none of the listed individuals had scienter and (b) if they did, any scienter cannot be imputed to the Company.

This part, Part V, focuses on (a). And Part VII focuses on (b). (Part VI provides a mid-way conclusion.)

The analysis here in Part V proceeds as follows.

The Court starts with a brief introduction. See Part V.A. It explains that the analysis will focus on the empty boxes associated with the Franchise President and Chief Operating Officer, and will proceed on the assumption (later to be tested) that they were aware of the relevant Company public statements.

The Court then sets out the three-part framework it will use for the analysis, <u>see</u> Part V.B, and then applies it, <u>see</u> Part V.C (part one), Part V.D (part two), and Part V.E (part three).

The landing point: a reasonable jury could conclude the Franchise President and the Chief Operating Officer had scienter as to statements 8, 9, and 10 --- and more briefing will be needed as to whether the Franchise President had scienter for statements 5, 6, and $7.^{22}$

A. Introduction

As noted, this Part zeroes in on what comes <u>before</u> imputation -- whether particular individuals themselves had scienter, "the
intent to deceive, manipulate, or defraud either knowingly or
recklessly." <u>Pamcah-UA Loc. 675 Pension Fund</u> v. <u>BT Grp. PLC</u>,
2021 WL 3415060, at *1 (3d Cir. Aug. 5, 2021).

Before getting underway with the analysis, take a brief look at the law in play here, <u>see</u> Part V.A.1, and consider both an important wrinkle given the nature of this case, <u>see</u> Part V.A.2, and the substance of the ten relevant statements, <u>see</u> Part V.A.3.

For reasons that are explained there, the Managing Director is discussed only in Part VII.

1. Law

In the large majority of securities fraud cases, there is no direct evidence put forward as to scienter, no proof of a defendant saying: I am doing this (making a particular public statement, for example) to trick ("deceive" or "manipulate") people. See, e.g., Herman & MacLean v. Huddleston, 459 U.S. 375, 391 n.30 (1983); Valicenti Advisory Servs., Inc. v. S.E.C., 198 F.3d 62, 65 (2d Cir. 1999).

Rather, a common way to show scienter is to point to a dissonance between (a) what a person knew and (b) what they said --- and to argue that from that dissonance, the necessary "intent to deceive" can be inferred.

If a person knows a drug company cherry-picked data to make a study look better than it was, but then says the results were "truly exceptional," without reservation --- how can what he knew and what he said live together in his mind? One possible answer: because he intended to deceive. See Alaska Elec.

Pension Fund v. Pharmacia Corp., 554 F.3d 342, 344-46, 351-52 (3d Cir. 2009) (holding scienter adequately alleged on the facts set out in this paragraph).

If a person knows about a company's very sharply contracting margins, but repeatedly and flatly says the company is facing no significant pressures as to the prices it can charge --- how to make sense of the disjunct between the two? An available explanation: the person intended to deceive. See Institutional Invs. Grp. v. Avaya, Inc., 564 F.3d 242, 267-280 (3d Cir. 2009) (holding scienter was adequately alleged on the facts set out in the paragraph).

Here, the Plaintiffs press an argument structured like the ones sketched out above.

They point to certain actions that were taken --- the making of the ten referenced statements. And they point to proof of what certain people knew when the statements were made. And from the asserted dissonance between these --- they infer that the individuals in question had scienter. See Plaintiffs' Letter (May 24, 2024) at 2-3; Memorandum in Opposition at 15-16; 21.

The Defendants' summary judgment motion argues there was no dissonance --- there was no real tension between what the relevant individuals knew and what the Company said. See Motion for Summary Judgment at 19; Reply Brief at 2, 13-15; Defendants' Letter (May 24, 2024) at 2-4. And in the absence of such dissonance, the Defendants say: no scienter.

2. A Complexity

Before going further, note an important wrinkle.

The Court's focus throughout this Part, Part V, is on asking whether a reasonable jury could find that the Chief Operating Officer and the Franchise President had scienter --- on the assumption they were aware of the relevant statements by the Company.

To explain why the Court makes this assumption for now, take a quick hypothetical.²³

The hypothetical: imagine a CFO who knows something (profits are falling) but says something else (profits are soaring). The explanation for this disjunct could very well be that the CFO had an intent to deceive, scienter.

But in a case like this one, in which the statements in question are a corporation's, things are different. The knowledge and the statement are not bundled together in a single person, as in the CFO example.

Rather, cases like this one are defined by a built-in divide. There is a person, who knows something. And there is a corporation, that says something.

This divide does not mean that there cannot be a dissonance between what is known and what is said. Indeed, there is always a logical contradiction between (a) profits are falling and (b) profits are soaring.

But scienter is what the '34 Act requires, not a logical dissonance. Accordingly, a logical dissonance does not matter for its own sake. It matters to the extent that it works as evidence of what is in a person's mind --- as a basis for inferring an intent to deceive, scienter.

In the typical case (where the person who knows and the person who speaks are one and the same), dissonance is almost always potential evidence of scienter. Why else, aside from wanting to deceive, would the CFO say profits are soaring when she knows they are falling?

But in a corporate imputation case like this one, logical dissonance is not always quite so clarifying.

To see why, stick with the CFO who knows profits are falling.

The hypothetical is structured along the lines of the Third Circuit cases set out in the prior section, Part V.A.I.

Imagine that one day, out of the blue, the company issues a press statement that says profits are soaring. There is a logical dissonance as before between knowledge (profits are falling) and statement (profits are soaring). But on these hypothesized facts, that dissonance does not prove anything about the CFO's mental state. She did not intend for anyone to be deceived by the press release. How could she? She had no idea it was coming.

Or imagine if the CFO (who, again, knows profits are falling) is on vacation when the 10-K is put together, and has zero involvement in its preparation. If the 10-K says profits are soaring, that, again, says little about the CFO having an intent to deceive.

The point is only this: for the disjunct between knowledge and statement to be a possible basis for inferring a mental state of scienter, the two must be somehow linked.

When it is the same person that has the knowledge and makes the statement --- then that person is, herself, the link.

But when a person has the knowledge and a corporation makes the statement --- then the link must be established in some other way.

The most basic way: by affirmatively showing that the person who had the knowledge was aware of the statement.

If the CFO knows profits are falling, but nonetheless is aware of a soon-to-be-filed 10-K that says profits are soaring --- that suggests she might have an intent to deceive, and provides a potential basis for inferring she has scienter.

Come back now to this case.

Here, scienter can be established on the Plaintiffs' chosen theory only by establishing at least some sort of link between (a) the knowledge of certain people (the Chief Operating Officer, the Franchise President, and the Managing Director), and (b) the ten public statements of the Company that are at issue. And as noted, that link may be based on awareness by the people of the statements.

To make things easier to follow, the Court breaks its analysis into two.

In this Part, Part V, the Court asks whether a reasonable jury could find that the Chief Operating Officer and the Franchise President had scienter --- proceeding on the assumption they were aware of the relevant Company statements.

And in Part VII, the Court circles back and tests this assumption --- to determine whether the evidence put forward actually supports it.²⁴

3. The Statements

Before going further, a last bit of background, as to the statements at issue here.

Statements 1 through 7 were made during July, September, and October of 2017, before the Drug application was submitted. See Part III.

The overall gist of these statements: the Company was conducting "phase III" Drug trials that were showing "positive top-line results," 25 and the Company was "[o]n-track" to submit a Drug application to the FDA by the end of the year. 26

Statements 8 through 10 were made during January and February of 2018, just after the Drug application was submitted. See Part III.

The overall gist of these statements: the Company had submitted the Drug application to the FDA "based on data from phase III" trials, 27 and was waiting to hear back.

B. A Three-Part Framework for the Analysis

In the context of a 10b-5 claim, as noted above, the "required state of mind is scienter --- the intent to deceive, manipulate, or defraud either knowingly or recklessly." Pamcah-UA Loc. 675
Pension Fund, 2021 WL 3415060, at *1; see generally Ernst & Ernst, 425 U.S. at 193 n.12.

This is <u>what</u>, among other things, a plaintiff must prove. "But \underline{how} does a court go about discerning whether the scienter bar has been cleared in a given case?" \underline{Wu} , 2024 WL 3163219, at *23 (cleaned up).

To organize the information, the Court will make use here of a three-part framework developed in another case, $\underline{\text{Wu}}$ v. $\underline{\text{GSX}}$ Techedu Inc.:

In Part VII, the Court also asks another question: whether any individual's scienter can be imputed to the Company.

²⁵ Complaint ¶ 403; Yadava Declaration, Ex. 37 at 5.

²⁶ Complaint ¶ 405; Yadava Declaration, Ex. 41 at 23.

²⁷ Complaint ¶ 422; Yadava Declaration, Ex. 61 at 5.

[F]ederal law focuses on a set of questions that can help distinguish between instances in which an allegedly false statement was made with scienter and instances in which it was not.

Three of those questions follow.

<u>First</u>, was the issue as to which the statement was made especially important to the Company?

This question is often discussed in terms of the "core operations" doctrine, or in terms of the sheer scale of the issue.

<u>Second</u>, was the issue as to which the statement was made especially important to the particular senior executive whose alleged scienter is in play?

And third, was there something that would have helped to cut through the noise --- to pique the executive's focus on the statement by suggesting a real possibility that it was false?

This [third] question is often discussed in terms of the metaphor of "red flags."

. . .

Red flags can come in different types. . . .

A first type of red flag: [evidence] that a person has been directly presented with information that suggests a strong possibility that a statement the person later makes is materially false or misleading.

A second sort of red flag is both less direct and less telling.

This type of red flag is a signal of possible danger around the curve. It provides a reason to investigate further before making a statement, to perceive possible trouble ahead, and slow down. It can be reckless within the meaning of the securities laws to ignore this sort of red flag, especially when it is bright, because what it conveys is unmistakable, and big, because it relates to something especially important.

Wu, 2024 WL 3163219, at *24-26 (cleaned up).28

 $[\]underline{\underline{Wu}}$ addressed a motion to dismiss, and this case is at the summary judgment stage. But no matter. $\underline{\underline{Wu}}$ simply lays out a framework that aims to distill down what some 10b-5 cases, at various stages, have said about where to look for indications of

C. Part One: Importance to the Company

To begin the scienter analysis as to the Chief Operating Officer and the Franchise President, start with the first part of the three-part Wu framework.

This part asks: "was the issue as to which the statement was made especially important to the Company?" $\underline{\text{Wu}}$, 2024 WL 3163219, at *24.

The Court's answer: yes.

The "issue" here is the Drug application's prospects, in the run-up to the end-of-2017 submission to the FDA.

There is evidence that Company officials had publicly suggested that the Drug could have annual sales of between \$4 and \$6 billion. See Cecchi Declaration, Ex. 134 at 1 (2015 news article, from when the Company acquired an entity that was then working to develop the Drug, stating: "[Company] executives said that [the Drug] could have peak annual sales of \$4 billion to \$6 billion").

scienter, especially in the context of the mental state of senior leaders of large organizations. See Wu, 2024 WL 3163219, at *24-26. Wu articulates a possible way to structure the analysis of scienter-related information, that might be applied whether that information is in the form of allegations (in a pleadings-stage case) or evidence (in a summary judgment-stage case). (And in any event, note that substantive law does not generally change depending on what stage a case is at. e.g., Anesthesia Advantage, Inc. v. Metz Grp., 912 F.2d 397, 404 n.8 (10th Cir. 1990); O'Farrell v. Twin Bros. Meats, 879 F. Supp. 478, 480 (E.D. Pa. 1995). There are some exceptions, as when information asymmetries suggest the need for application of different substantive law at the pleadings stage versus the evidence stage. <u>See</u>, <u>e.g.</u>, <u>Caduceus</u>, <u>Inc.</u> v. Univ. Physician Grp., 2024 WL 303845, at *6 (D.N.J. Jan. 26, 2024); Prestan Prods. LLC v. Innosonian America, LLC, 2024 WL 278985, at *5 n.17 (D.N.J. Jan. 25, 2024). And those sorts of considerations have at times been applied in the securities law context and led to a distinction between pleadings-stage law and evidence-stage See, e.g., N. Fork Partners Inv. Holdings, LLC v. Bracken, 2023 WL 3871903, at *14 (S.D.N.Y. June 7, 2023) (discussing how the group pleading doctrine is not available at the summary judgment stage); S.E.C. v. Espuelas, 699 F. Supp. 2d 655, 662 (S.D.N.Y. 2010) (same). But this is no reason to leave ${\tt Wu}$ behind --- as noted, its framework is solely used here as a tool for organizing the scienter-related information.)

Additionally, there is proof that the Drug was publicly perceived as especially important to the Company. Part of the reason why: the Company was having issues with the development of a separate product, and there is evidence of public perception that the Drug would need to carry the load.²⁹

Bottom line: a reasonable jury could conclude that the Drug was no easy-to-miss piece of the Company's bigger picture. It was no backwater. It was central, especially in the period during which the relevant statements were made. Accordingly, a jury could infer that major developments as to moving the Drug to market, including the progress of the Drug application, were more likely to command the attention of Company leaders, and were less likely to be drowned out by the din of everyday corporate management.

D. Part Two: Importance to the Individuals

Turn now to the next question in the three-part <u>Wu</u> framework: "was the issue as to which the statement was made especially important to the particular senior executive whose alleged scienter is in play?" Id.

Same "issue": the prospects for the end-of-2017 FDA Drug application. And same answer: yes.

See, e.g., Cecchi Declaration, Ex. 136 at 1 (October 2017 analyst report: given development failures with another product, the Drug was "[t]he Last Hope pressure to succeed . . . [was] now almost exclusively on [the Drug] For now, the [Company] relies on [the Drug] to outperform already lofty . . . expectations"); Cecchi Declaration, Ex. 137 at 1 (October 2017 analyst report: "[the Company] reported . . . results that severely disappointed relative to expectations on [a different drug in development] [T]he summation of our analysis is that the company is heavily dependent on [success with the Drug]"); Cecchi Declaration, Ex. 135 at 1 (October 2017 analyst report, noting that the other drug had likely failed, but that the outlook for the Company was not negative, because "we still believe that [the Drug] will be a meaningful contributor to long-term revenues . . . We continue to expect positive data from [phase III Drug approval studies], which should bolster [the Drug's] approval prospect (NDA submission . . . expected by [year end 2017])").

1. The Franchise President

The Franchise President was the head of the Franchise. See Defendants' Rule 56 Statement \P 6. That was from April 2017 through to at least February of 2018, when the last of the ten statements here was made. See id. Prior to that, she held a lower-ranking executive position in the Franchise. See id. at \P 6.

The Franchise was responsible for development of the Drug. See \underline{id} . at ¶¶ 1, 4.30 But the Franchise was also big and important, one of the Company's "two key business units." Id. at ¶ 1.

Running it, the Franchise President was busy with any number of competing concerns. She might not have zeroed-in on the Drug and its development. But there is a good deal of evidence that she did.

<u>First</u>, there is some evidence that the Franchise President was, at least ex officio, responsible for overseeing the clinical development of the Drug, <u>see</u> Defendants' Rule 56 Statement $\P\P$ 1, 6, and its "regulatory matters." <u>See id</u>. ("[R]egulatory matters" presumably included seeking FDA approval to bring the Drug to market.)³¹

The Drug was initially developed by Receptos, Inc. See Defendants' Rule 56 Statement \P 3. In 2015, the Company bought Receptos. See id. at \P 4. From that point, the development of the Drug became the responsibility of the Franchise. See id.

A qualification. The evidence in the text is drawn from statements from the Defendants in their Rule 56 statement. These were made as to the Chief Operating Officer. The Chief Operating Officer was the President of the Franchise until April See id. at ¶ 5. At that point, the Franchise See Defendants' Rule 56 Statement \P 6. President took over. their Rule 56 statement, the Defendants state that, when the Chief Operating Officer left the job, he was "no longer" responsible for overseeing clinical development or regulatory matters for the Drug. See id. at \P 6. From that, it is a reasonable inference, of the sort the Plaintiff is entitled to, see, e.g., Canada v. Samuel Grossi & Sons, Inc., 49 F.4th 340, 345 (3d Cir. 2022), that such responsibilities rested with whoever was president of the Franchise --- and thus were part of the Franchise President's purview from April 2017 (when she took the reins) through February 2018 (the last relevant moment in time here).

<u>Second</u>, there is testimony that suggests the Franchise President played a direct, hands-on role in communicating with the public about the Drug.

For example, in preparing certain public Company communications, "to the extent there was a scientific topic or a clinical development topic, a substantive piece of information that the company was going to cover on the [conference] call . . . generally, clinical development issues were handled by the franchise heads." Cecchi Declaration, Ex. 1, Deposition of Chief Operating Officer at 29:10-23.

And another example: the Franchise President publicly presented slides in October 2017 that discussed the Company's end-of-2017 submission of the Drug application to the FDA. See Defendants' Rule 56 Statement \P 44.

Third, there is proof that the Franchise President was closely involved in issues related to the Drug application.

For example, she was informed of the existence of the Drug Metabolite during the summer of 2017, both in person and via email. See, e.g., Cecchi Declaration, Ex. 3 at CELG-AMF 01030045-46 (July 2017 email from the Managing Director, informing her of the Metabolite's existence); Cecchi Declaration, Ex. 117 at CELG-AMF 04746683 (July 2017 email from the Vice President, Regulatory Affairs for the Franchise, stating that he talked to the Franchise President about the Metabolite).

Another example: the Franchise President received a copy of the briefing book, of which more later, that the Company sent to the FDA in October of 2017, <u>see</u> Plaintiffs' Letter (May 24, 2024), Ex. D at CELG-AMF 00934481, and reviewed the FDA's feedback when it came back a month later. <u>See</u> Cecchi Declaration, Ex. 6 at CELG-AMF 04619727.

And there is evidence that when it came to Drug development the Franchise President was a decision-maker --- not a passive, onthe-cc-line observer of others' affairs.

For example, when the FDA sent over its feedback on the referenced briefing book, a Company executive outlined a possible plan of action, and the Franchise President stopped the trains to ensure that she would have a chance to weigh in: "[t]his course of action has not been discussed with me. I will reply tomorrow once I have reviewed the FDA feedback." Cecchi Declaration, Ex. 127 at CELG-AMF 04643283.

Other evidence is to a similar effect. For example, the Franchise President appears to have been actively involved in contingency planning conversations about what to do if there was

not enough time to work through the Drug application. See Cecchi Declaration, Ex. 61 at CELG-AMF 00935701. These conversations generally assumed knowledge about the application. See, e.g., Cecchi Declaration, Ex. 61 at CELG-AMF 00935701 (November of 2020 email from Franchise executive talking about the "team's proposal" to the FDA, and what to do if the FDA did not accept it, without further details). And the Franchise President both participated in those conversations as a decision-maker, see Cecchi Declaration, Ex. 61 at CELG-AMF 00935701 (indicating agreement with a course of action proposed by another executive), and undertook to provide up-the-chain updates. See Cecchi Declaration, Ex. 63 at CELG-AMF 00936009 (forwarding an email on this topic to the Chief Operating Officer, and saying she would "keep [him] posted" on relevant discussions).

Overall, the evidence suggests a senior executive opting to dig in on an important issue. Not a pulled-in-many-directions leader occasionally looking in from 30,000 feet away.

In short: there is ample proof that the Drug application was a subject that the Franchise President was closely and actively focused on.

2. The Chief Operating Officer

Turn now to the Chief Operating Officer, and start with his employment history.

From 2010 until April of 2017, he was the president of the Franchise. See Defendants' Rule 56 Statement ¶ 5. In that capacity, he was the immediate predecessor of the Franchise President. See id. at ¶¶ 5-6. He was president of the Franchise during the period when the Company bought Receptos, see footnote 30, and when development of the Drug became the Franchise's responsibility, in August 2015. See Defendants' Rule 56 Statement ¶ 4.

While president of the Franchise, he was seemingly responsible for overseeing the clinical development of the Drug, as well as "regulatory matters," $\underline{\text{see}}$ $\underline{\text{id}}$. at \P 6, presumably including seeking FDA approval for the Drug.

In April 2017, he was promoted and became the Company's Chief Operating Officer. See id. In that capacity, the Franchise President was his direct report. See id.

The record put before the Court contains a good deal of evidence that the Chief Operating Officer remained involved in the development of the Drug between April 2017 (when he was

promoted) and early 2018 (when the last of the ten relevant statements was made). Some examples:

- In July 2017, the Chief Operating Officer was informed of the existence of the Metabolite. <u>See</u>, <u>e.g.</u>, Cecchi Declaration, Ex. 3 at CELG-AMF 01030045-46 (July 2017 email to the Chief Operating Officer).
- The Chief Operating Officer weighed in on planning a meeting at which the Company intended to seek feedback from the FDA as to the Drug. See Cecchi Declaration, Ex. 4 at CELG-AMF 00935619 (email chain in which another executive proposed attendees, and the Chief Operating Officer responded: "I would suggest that we discuss. We need to do better. We should have [certain named Company executives] at the meeting. I will assume that that will happen. This is too important to not be aligned.").
- When the Company eventually received critical feedback from the FDA on the then-upcoming Drug application, the Chief Operating Officer was informed in near-real time --- the day after the feedback came in, at the same time as the Franchise President. Compare Cecchi Declaration, Ex. 127 at CELG-AMF 04643284 (November 22, 2017 email chain informing the Chief Operating Officer, Franchise President, and a key Drug development team leader about the FDA feedback) with Defendants' Rule 56 Statement ¶ 52 (the Company received the feedback on November 21).
- Six days later, the Chief Operating Officer received a tracker, conveyed by the Franchise President, that set out information about the status of the Drug submission. See Cecchi Declaration, Ex. 6 at CELG-AMF 04619727. The tracker assumed both a good deal of technical knowledge and relatively close-in familiarity with respect to development of the Drug.
- And a final example: during the late fall of 2017, the Company's Chief Medical Officer reached out to the Chief Operating Officer to set up a time to "discuss the FDA feedback and the status of the [Drug] submission [to the FDA]." Cecchi Declaration, Ex. 5 at CELG-AMF 04643281. The Chief Operating Officer said they should talk that day, and that the Chief Medical Officer should include a specific member of the Drug development team. See id.

E. Part Three: Direct Evidence

Where things stand: during the period when the relevant statements were made, there is ample evidence that the Drug was an important focal point for (a) the Company, see Part V.C, and (b) both the Franchise President and the Chief Operating Officer. See Part V.D.

Turn now to the much more important evidence here as to scienter: the direct evidence. See generally Wu, 2024 WL 3163219, at *25 (the third part of the three-part framework for analyzing scienter: whether there are indications "that a person has been directly presented with information that suggests a strong possibility that a [later] statement . . . is materially false or misleading").

And recall throughout: for present purposes the Court analyzes a given person's scienter on the assumption that he or she was aware of the Company statements at issue. See generally Part V.A.2.

1. The Franchise President: Statements 5-7

Start with the Franchise President's mental state for the period that covers statement 5, 6, and 7.

The Plaintiffs' core argument, <u>see</u> Part V.A.1, is that there was a tension between (a) these statements and (b) what the evidence shows the Franchise President knew --- and from this discord, a reasonable jury could infer that the Franchise President had scienter.

What did the Franchise President know by the time period when Company statements 5, 6, and 7 were made? Two main things. Take these one at a time below.

a. The July 25, 2017 Email

On July 25, 2017, the Franchise President received an email from the Managing Director that said the Metabolite had been discovered. See Cecchi Declaration, Ex. 3 at CELG-AMF 01030045.

But as set out below, there was simply no meaningful dissonance between knowledge of the discovery of the Metabolite and statements 5, 6, and 7 --- statements that essentially indicated that the Company was headed to an end-of-2017 Drug application to the FDA. See generally Part V.A.3 (describing the statements).

There are different sorts of metabolites. See Cecchi Declaration, Ex. 9, Report of Dr. Frederick Peter Guengerich,

Ph.D ¶¶ 23-24, 53; Cecchi Declaration, Ex. 106, FDA, HHS, and CDER "Guidance for Industry Safety Testing of Drug Metabolites," at 3-5; Cecchi Declaration, Ex. 107 (Deposition of Matthew Lamb) at 41:23-43:12; Cecchi Declaration, Ex. 108, "Approaches to the Assessment of Stable and Chemically Reactive Drug Metabolites in Early Clinical Trials" at 1-4. Some cause major problems, others do not. See Cecchi Declaration, Ex. 9 ¶¶ 23-24, 53; Cecchi Declaration, Ex. 106 at 3, 5-6; Cecchi Declaration, Ex. 108 at 1-4.

Here, upon being told by email of the Metabolite, the Franchise President was also told by the Managing Director, in the same email, that "a lot of work" had been done "to better understand the situation and potential implications," and the "[p]reliminary data indicates that our story remains intact and that approvability is not impacted by this finding." Cecchi Declaration, Ex. 3 at CELG-AMF 01030045. The email went on:

All the activities that could be done to qualify [the Metabolite] have been conducted or are on-going, and recent feedback from ex-FDA reviewers (tox[icology], clin[ical] pharm[acology] and division director level) indicates that our plan/data should be acceptable to the [FDA] and allow us to keep the submission on schedule.

Id.

The Franchise President was an active and fluent executive, closely focused on the Drug and its development. See Part V.D.

But the Managing Director was much closer to the work, and had been for years. From 2016, the Managing Director had led the part of the Company that was directly developing the Drug, and before that he had been a leader at the entity (Receptos) that has been developing the Drug before the Company bought it. See Defendants' Rule 56 Statement ¶¶ 3, 8. As befitted his position, the Managing Director was heavily involved in discussions with Drug team members throughout 2017 about the Metabolite and its potential impacts. See, e.g., Cecchi Declaration, Ex. 15 at CELG-AMF 01076636; Ex. 21 at CELG-AMF 01229069-70; Cecchi Declaration, Ex. 24 at CELG-AMF 0107058-81; Cecchi Declaration, Ex. 32 at CELG-AMF 01312019; Cecchi Declaration, Ex. 57 at CELG-AMF 01032661; Ex. 127 at CELG-AMF 04643283.

In short, the Managing Director was a person to defer to when he said the Metabolite would not trigger any major problems.

And moreover, the explanation the Managing Director provided was no just-trust-me assurance. It was thoughtful, detailed, and full --- only a short excerpt is provided above.

In light of this, and in light of the Managing Director's long, closer-to-the-ground experience with the Drug --- there was no need to peek behind the curtain of what he had said. The Managing Director assured the Franchise President that the Metabolite would not cause a concern, and the Franchise President was entitled to take that to the bank.

In short: there is no reason to think there would have been any meaningful tension in the Franchise President's mind between (a) the Company's statements that the Drug application would be submitted by the end of 2017 and (b) the knowledge that the Franchise President had as of July 2017 --- that there was a Drug metabolite, but that it would not prevent making the "the [FDA] submission on schedule." Cecchi Declaration, Ex. 3 at CELG-AMF 01030045.

Numerous cases support the conclusion that, in the circumstance sketched out above, learning about the Metabolite was not, standing alone, sufficient to support an inference of scienter. See Winer Fam. Tr. v. Queen, 503 F.3d 319, 327-330 (3d Cir. 2007) (no scienter where executive touted the purchase of a facility, and said the facility required "minimal improvements," though it actually needed an expensive overhaul --- because there was no evidence the executive knew the facility needed an overhaul when the statements were made); Nguyen v. Endologix, Inc., 962 F.3d 405, 408-12, 415-16 (9th Cir. 2020) (no scienter where executives made positive statements about a drug application --- with knowledge of a potential issue, but without proof that the executives knew the issue would impact the application); In re Genzyme Corp. Sec. Litig., 754 F.3d 31, 34-39, 41-42 (1st Cir. 2014) (no scienter where defendants made optimistic statements about a drug approval timeline, though they knew about a potentially negative FDA inspection --because there was no evidence the defendants knew at the time that the FDA inspection would impact the drug approval timeline); City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Waters Corp., 632 F.3d 751, 758-60 (1st Cir. 2011) (no scienter where defendants knew about regulatory change and did not disclose it, where there were not sufficient allegations that they knew it would impact their business); In re Columbia Laby's., Inc. Sec. Litig., 2013 WL 5719500, *5-7 (D.N.J. Oct. 21, 2013) (no scienter where company knew about certain study results, which later led to FDA denial of their new drug application, because there were not sufficient allegations the company knew the results conflicted with an FDA requirement for the application); cf. Lungu v. Antares Pharma Inc., 2022 WL 212309, at *4-6 (3d Cir. Jan. 25, 2022) (statements by drug company touting results of drug study not misleading, even

though they did not disclose certain specific information about a possible risk); City of Edinburgh Council v. Pfizer, Inc., 754 F.3d 159, 170-171 (3d Cir. 2014) (statement not materially misleading where it indicated that certain studies were going well; there were reasons to be concerned about the results, but there were differences of opinion as to how to interpret those studies).³²

b. The Briefing Book

Aside from the July 25, 2017 email (which does not suggest scienter, <u>see</u> Part V.E.1.a), there is one other substantial piece of knowledge the Franchise President had at the time statements 5, 6, and 7 were made. Namely, on October 20, 2017 she received an email that attached a so-called "briefing [book]." <u>See</u> Plaintiffs' Letter (May 24, 2024), Ex. D at CELG-AMF 00934481.

Some background at the outset on a briefing book.

The Company, as noted, was gearing up for an end-of-2017 Drug application --- and in the run-up to the filing of such applications, the FDA generally encourages applicants to schedule a sit-down, to provide an informal sense of what the FDA will soon be asked to assess. See Defendants' Rule 56 Statement ¶ 45. The typical prelude to the meeting: submission of a "briefing book" to the FDA that includes "[a] brief summary of the . . . studies to be submitted in the application." Id.

Here, the Company submitted such a briefing book, in late October 2017. See id. at ¶ 46. Per the book, the Company wanted to discuss a "proposal" to "provide additional clinical pharmacology data regarding . . . the recently identified . . . Metabolite . . . early in the [Drug

Recall that Judge Vazquez held that the Chief Operating Officer did not have scienter for statements 1 to 7, when the core information he had before him was the Metabolite email discussed in this section. See Part IV.A. And recall that the Court today, under law of the case principles, has extended Judge Vazquez's holding, and concluded that the Franchise President did not have scienter for statements 1 to 4, when the core information she had before her was the same Metabolite The analysis in this section, Part email. See Part IV.B. V.E.1.a, shows that the law of the case conclusions reached in Part IV.A and Part IV.B were also, in the Court's judgment, correct on the merits.

application] review period." <u>See</u> Plaintiffs' Letter (May 24, 2024), Ex. D at CELG-AMF 00934490.

To see why this matters, a closer look is needed at a part of the Plaintiffs' overall theory of the case. It is as follows:

After the Metabolite was detected during the summer of 2017, the end-of-the-year schedule for the Drug application would plainly be hard to make work. See Opposition Brief at 6-9, 16-20. There was simply not much time left to do the sorts of high quality and long-term studies that the FDA expects as to major metabolites. 33 See Opposition Brief at 16-20. This implied a large risk that was never disclosed. Namely, the risk that the FDA could reject ("refuse to file") the Drug application as incomplete, because the Company would not be able to include the sorts of studies the FDA expects. See Opposition Brief at 7-8, 11-12.34

And that is where the briefing book comes in.

Via the briefing book, the Company asked for more time to conduct studies as to the Metabolite. How to get more time? By asking that the Drug application be made at the end of 2017 --- but with Metabolite studies to be submitted later. <u>See</u> Plaintiffs' Letter (May 24, 2024), Ex. D at CELG-AMF 00934490.

For evidence in the record as to how long it can take to do meaningful metabolite studies, see Cecchi Declaration, Ex. 9 ¶¶ 99-100; Cecchi Declaration, Ex. 31 at CELG-AMF 01291786 (15 months); Cecchi Declaration, Ex. 38 (6 months); id. (3 or 4 years); Cecchi Declaration, Ex. 76 at CELG-AMF 0091621 (48 months); id. at CELG-AMF 00916212 (12 months); Cecchi Declaration, Ex. 99 at FDACDER001911 (17 months); see also Cecchi Declaration, Ex. 15 at CELG-AMF 01076638 (projected NDA delay of 1 to 2 quarters); Cecchi Declaration, Ex. 24 at CELG-AMF 01070581 (projected 8-month delay in NDA submission to finish toxicology studies).

A key legal premise of the Plaintiffs' theory is that saying to the public we-will-file-an-FDA-application is tantamount to saying we-will-file-a-reasonably-complete-FDA application. (And perhaps all the more so because the Company had previously said the Drug application was "on track." See Weiner v. Quaker Oats Co., 129 F.3d 310, 315-18 (3d Cir. 1997) (explaining, among other things, how a company's prior statements impact how its later statements are understood by the public)). The Court here is not called upon to evaluate whether any of the ten Company statements were false or misleading. This is because the Defendants move for summary judgment just on scienter grounds.

There was, in short, a risk (that there would not be enough time to get the FDA the Metabolite studies it expected) and there was a possible mitigant (try to get more time). 35

From this, the Plaintiffs essentially invite the Court to reach the following conclusions:

- Asking for more time was a poor and all-but useless mitigant, because it would have barely whittled down the risk of a refusal to file. The FDA was very likely to say no. And even if it said yes: the tests proposed to be submitted after the Drug application were major and complex ones; they might not be completed even with an extension; they could fail and doom the application; or they could also suggest new problems with the Drug that then would need further exploring.
- A reasonable jury could conclude that none of this would have been missed by an executive as active and involved as the Franchise President. It was therefore understood that the risk of an FDA refusal to file started out as a very large one (because there was fundamentally not enough time for appropriate studies), and that risk was not meaningfully trimmed away by the request for an extension.
- Moreover, a reasonable jury could conclude that reaching for such a weak mitigant was proof that, in the Franchise President's mind, the risk of a refusal-to-file outcome was a large one --- that needed to be addressed even with a tool that was unlikely to make a difference. The felt need to seek a last-minute time extension ask was itself evidence of knowledge of a high likelihood of a refusal to file of the Drug application.

The problem with this argument from the Plaintiffs, and with the Defendants' response to it, is that some seemingly important

In securities law, risks and mitigants often run together. Take, for example, a clothing manufacturer. If the likelihood that its factory will catch fire is high enough, and if the anticipated negative outcome of such a fire is bad enough --- then disclosure of fire risk may be called for. But mitigants (a sprinkler system, say, or all-metal construction) can reduce the likelihood of fire and/or soften the worst of its negative impact. These mitigants can dramatically reduce the probability-adjusted impact of any fire --- perhaps to the point that a fire risk no longer needs to be disclosed.

propositions appear to be assumed or asserted in the legal papers, but not substantiated with evidence.

As to the risk, for example: looked at from the moment when the briefing book was submitted, could full and adequate testing on the Metabolite (to normal FDA standards) have been completed by the end of 2017 without an extension? With an extension?

As to the mitigant, for example: roughly how unusual was it for the FDA to grant extensions? What exactly transpired at the March 2017 FDA/Company meeting?

And as to all of these issues: did the Franchise President have a direct sense as to the answers, or were they just the sorts of things that a fluent and active Company executive would have roughly been expected to know?

It is no mystery why there are gaps in the papers. The parties' briefs were exceptionally strong and thoughtful. But there were a great many issues to cover. (Including some that were the subject of an entirely separate judicial opinion. See In re Celgene Corp., Inc. Sec. Litig., 2024 WL 3503486 (D.N.J. July 23, 2024).) The briefs were therefore necessarily spread somewhat thin, and they muster facts only glancingly as to the issues raised by the above, and cite relatively few cases, too.

How to proceed?

One possibility is to go forward by inference. There is record evidence that suggests long-term studies are generally understood to be a necessary component of a complete FDA drug application. And, if this was a widespread understanding --- it is hard to see how it could have been missed by the Franchise President. See generally Part V.D.I. And there are passages in the briefing book that suggest that the plan was to produce long-term studies not just after the Drug application was submitted, but long after. Moreover, there is information in

See Cecchi Declaration, Ex. 29 at CELG-AMF 01301571-72; Cecchi Declaration, Ex. 30 at CELG-AMF 01074874; Cecchi Declaration, Ex. 44 $\P\P$ 22-31; cf. Cecchi Declaration, Ex. 40 \P 19; Cecchi Declaration, Ex. 107 at 39:2-18.

³⁷ See Plaintiffs' Letter (May 24, 2024) Ex. D at CELG-AMF 00934605 ("validation with . . . long-term storage stability (LTS) assessments . . . is ongoing as required to cover samples from the previously completed clinical studies. . . . Validation report addenda will be prepared following completion of LTS assessments at intervals of approximately 1, 6, 12, 15, 18, 24, 30, and 36 months."); id. at CELG-AMF 00934606 (120-days [after the NDA submission] safety update: Addendum to [Metabolite]

the briefing book that suggests that the various long-term studies were understood to be "central to having a complete [Drug application.]" Plaintiffs' Letter (May 24, 2024), Ex. D at CELG-AMF 00934606.

But proceeding on inference is less than ideal. And all the more so here, where some of the underlying issues are technical. Moreover, the possible inferences sketched out just above do not cover all the questions laid out a few paragraphs prior. In addition, this is a wide-reaching case --- there are parts of the record that the parties have worked to build, but that are not before the Court.

Against this backdrop, the parties should be given a chance to supplement their submissions to the Court factually (and also with on-point cases). An order that will issue shortly will set a schedule for doing so.

* * *

Before moving on, two final points should be noted.

First, Judge Vazquez previously held that the Managing Director's receipt of the briefing book, which sought the extension, cut in favor of the conclusion that the Managing Director had scienter. See Argument Transcript at 107:4-108:10. But that holding does not compel the conclusion that the Franchise President had scienter. The reason: at the point when each of them looked at the briefing book --- there was much more evidence of the Managing Director's scienter than of the Franchise President's.³⁸

<u>Second</u>, some of the arguments that the Defendants have raised to this point as to the Franchise President and the briefing book are not persuasive (and do not warrant further briefing in the above-referenced supplemental submission).

Tick through five of them here.

(1)

plasma assay validation report 185723 to include . . . some ongoing LTS assessments").

³⁸ Some of the scienter evidence that runs just to the Managing Director: Cecchi Declaration, Ex. 15 at CELG-AMF 01076636; Cecchi Declaration, Ex. 20 at CELG-AMF 01248050, 055; Cecchi Declaration, Ex. 24 CELG-AMF_01070580-81; Cecchi Declaration, Ex. 27 at CELG-AMF 01049279; Ex. 56 at CELG-AMF 01301194 & Ex. 57 at CELG-AMF 01032661.

The Defendants suggest that while the Franchise President was emailed the briefing book --- perhaps she did not read it. See Defendants' Letter (May 31, 2024) at 2. That is an argument the Defendants are free to make to the jury, if it comes to it. But the Plaintiffs are entitled to all reasonable inferences at this stage of the proceedings. See Dejewski v. Nat'l Beverage Corp., 2024 WL 2744981, at *5 n.11 (D.N.J. May 29, 2024) (collecting cases). And one of those inferences is that people generally read their emails. See Ball v. Kotter, 723 F.3d 813, 830 (7th Cir. 2013); Kennell v. Gates, 215 F.3d 825, 829 (8th Cir. 2000); United States v. Valentino, 2023 WL 361077, at *19 (E.D. Pa. Jan. 23, 2023); Robinson v. Pine Hills Mgmt. Co., 2021 WL 62594, at *2 (D. Colo. Jan. 7, 2021).

To be sure, there may be times when this inference is not reasonable. For example, spam emails are routinely moved to the trash, unread. And people may be less likely to read emails that come in when they are traveling or sick, or from an old account that they peek in on only rarely.

But none of that is relevant here. The briefing book was not, for example, a blast email. It was sent on a one-to-one basis, from one senior executive directly to another, see Plaintiffs' Letter (May 24, 2024), Ex. D at CELG-AMF 00934481 --- on a highly important topic, and apparently based on a prior conversation between the sender and the receiver. See id. It is reasonable enough to infer the email was read, and the Plaintiffs are entitled to that inference. See Dejewski, 2024 WL 2744981, at *5 n.11.

(2)

The Defendants also make a passing reference to the length of the briefing book. <u>See</u> Defendants' Letter (May 31, 2024) at 2. The suggestion seems to be that the Franchise President did not page through it.

But this is a variant on the did-not-read-the-email argument, and it fails for many of the same reasons.

And moreover, the key point in the briefing book --- that the Company would be asking the FDA for permission to do post-application testing --- was set out on the first sentence of the first page of the briefing book. See Plaintiffs' Letter (May 24, 2024), Ex. D at CELG-AMF 00934490; see generally Dejewski, 2024 WL 2744981, at *8-9. That point was included in a clearly marked Executive Summary section. See Plaintiffs' Letter (May 24, 2024), Ex. D at CELG-AMF 00934490. And the sentence in question included a proposed change, see id. --- one that the Company regulatory affairs executive who sent the email had

apparently made, and presumably wanted his superior (the Franchise President) to review and reflect on.

In addition, a reasonable jury could readily conclude that the key point --- that an extension was needed because there might otherwise not be time for the sort of long-term studies that are "central" to filing a "complete" Drug application, see id. at CELG-AMF 00934606 --- was hard to miss. It came up throughout the briefing book, and would have been apparent from the book's first sentence, which explicitly linked the ask for a time extension to the proposal to make a late submission of Metabolite data. See id. at CELG-AMF 0093449.

The Defendants can press a needle-in-the-haystack argument to the jury. But that argument is not so strong that the Court can rely on it here --- as a basis for taking this case away from the jury, by granting the Defendants' summary judgment motion. See Dejewski, 2024 WL 2744981, at *8-9.

(3)

The Defendants also suggest that the Franchise President's mental state is out of bounds here, because she was dismissed from the case at the Rule 12(b)(6) stage. <u>See</u> Defendants' Letter (May 24, 2024) at 2-4.

But the Defendants point to no on-point case that supports the argument that scienter imputation can work only if the individual in question is a defendant.

And in any event, the Defendants' argument is not persuasive. Under <u>Janus</u>, 564 U.S. at 141-42, a person who is not a statement-maker cannot ordinarily be a 10b-5 defendant. And federal courts have routinely held that knowledge can be imputed to a corporation from a non-statement-maker. <u>See Patel</u>, 2016 WL 1629325, at *15 n.38; <u>Pa. Pub. Sch. Employees' Ret. Sys.</u>, 874 F. Supp. 2d at 372 (S.D.N.Y. 2012).

(4)

Next, the Defendants note that Judge Vazquez held that the Chief Operating Officer did not have scienter as of October 2017, see Argument Transcript at 108:11-18 --- even though, by that point, the Chief Operating Officer was "aware" of the book. See Defendants' Letter (May 31, 2024).

But this is no contradiction. The evidence is that the Chief Operating Officer was "aware in general that we had sent in a briefing book to the FDA and were waiting to hear from them." Lead Plaintiff's Response Pursuant to Local Civil Rule 56.1 to Defendants' (Corrected) Statement Of Material Facts Not In

Dispute (Docket Entry 260) ¶ 138. And there is all the difference between knowing that a book exists "in general" and knowing what it says. A person who has read the how-to manual can be expected to know how to put together a cabinet. But not a person who is just "aware in general" that a how-to manual exists.

(5)

Finally, the Defendants say that Judge Vazquez's "line in the sand" on the briefing book turned on when it was received by the FDA, not on when it was seen by a given person. See Defendants' Letter at 2 (May 31, 2024). But that is not what Judge Vazquez held. See Argument Transcript 106:22-108:10. And such a holding would have made little sense: the briefing book (like most other information) would have made its impression when a person saw it --- not later, when someone else did.

2. Statements 8-10

Now look to the last set of statements --- 8, 9, and 10, made in early 2018, after the Drug application had been submitted. See Part V.A.3 (describing the statements).

As to these statements and this period, similar evidence undergirds the scienter analysis as to the Franchise President and the Chief Operating Officer. Their mental states are therefore taken up together.³⁹

* * *

To better understand the early 2018 mental state of the Franchise President and the Chief Operating Officer, look back a bit --- to the roughly six-month period that ran from early July 2017.

During that period, there was ample reason to be concerned about whether a reasonably complete Drug application could be submitted by the end of 2017. Testing for metabolites is often (or typically) done <u>before</u> phase III drug trials.⁴⁰ But in connection with the Drug, phase III trials had long been

Recall: the analysis here proceeds on the assumption that they were aware of the statements. See Part V.A.2.

 $[\]underline{\text{See}}$ Cecchi Declaration, Ex. 15 at CELG-AMF 01076636; Cecchi Declaration, Ex. 16 at 35:11-36:24; Cecchi Declaration, Ex. 107 at 43:5-10.

underway and were near completion⁴¹ --- but the Metabolite had only been "definitively confirmed" during the summer of 2017. Yadava Declaration, Ex. 21 at CELG-AMF 01303197. This was late for an end-of-the-year Drug application, given the Metabolite testing the FDA would be expecting in a complete application.

A reasonable jury could readily conclude that all of the above would have been abundantly clear to the Franchise President and the Chief Operating Officer, because a reasonable jury could conclude:

First, they were actively involved in Drug development. See Part V.D.

 $\underline{\text{Second}}$, the extreme time-crunch brought on by the late Metabolite discovery was, during the summer and fall of 2017, consuming for numerous Franchise employees, and was one of the most critical overall issues related to the Drug. 42 The

^{41 &}lt;u>See Yadava Declaration</u>, Ex. 2, Company Press Release, at 1 (July 2015 press release noting that phase III trials are "ongoing"); Yadava Declaration, Ex. 12, Company Press Release, at 1 (announcing the results of a 12-month phase III trial, in February 2017); Yadava Declaration, Ex. 20, Company Press Release, at 1 (May 2017, announcing positive results for a two-year long phase III trial).

See Cecchi Declaration, Ex. 27 at CELG-AMF 01049279-CELG-AMF 01049281 (May 2017 email from Drug team leader to the Managing Director stating "the December timeframe [to submit the NDA] is extremely optimistic. Anything that slows down the progress . . . will put that timeline in jeopardy," and asking for the Chief Operating Officer to be looped in so "[w]e can leverage his being brought up to speed to ask for the mobilization of the resource that we talked about to be assigned to the project"); Cecchi Declaration, Ex. 28 at CELG-AMF 01070518-CELG-AMF 01070519 (May 2017 email from Drug team leader outlining the "urgency" needed to resolve the impact of the likely metabolite, stating it could have a "significant negative impact on the NDA deliverables and timeline," and outlining relevant meetings and discussions); see also Cecchi Declaration, Ex. 29 at CELG-AMF 01301572 (June 2017 email exchange between two Drug team members); compare Cecchi Declaration, Ex. 66 at CELG-AMF 00934369 (Drug team email chain indicating that high-up Drug team members had implemented "regular touch base/communication" about the progress of the Drug application) with Cecchi Declaration, Ex. 107 at 68:3-21 (testimony from prominent Franchise executive that this was done because "there was a lot of work to be done between that time point in August and the

Franchise President and the Chief Operating Officer could hardly have been unaware of this. 43

Third, the briefing book request for an extension was itself based on one main idea: that without an extension, there was a real likelihood that there would not be enough time to prepare a complete Drug application. The Franchise President was aware of the briefing book ask during October 2017. See Plaintiffs' Letter (May 24, 2024), Ex. D at CELG-AMF 00934481. And the Chief Operating Officer was aware of it, too --- certainly by November 2017, when he learned of the FDA's response to the briefing book. See Cecchi Declaration, Ex. 127 at CELG-AMF 04643283.

And <u>fourth</u>, during the fall of 2017, the Franchise President and other Company executives began discussing certain (expensive) contingency plans, involving a priority review voucher. <u>See</u>, <u>e.g.</u>, Cecchi Declaration, Ex 61 at CELG-AMF 00935701 (November 20, 2017 email back and forth between the Franchise President and the Franchise's Vice President, Regulatory Affairs).

This discussion was premised, in part, on an understanding that as things stood there was a major problem. "In the situation that the FDA doesn't accept the proposed [Drug] strategy [of allowing for the submission of late Metabolite studies]," Cecchi Declaration, Ex. 63 at CELG-AMF 00936009, a voucher fix could be tried. "[T]hat would potentially enable us to keep the current timeline." Id. But "potentially" is no guarantee --- and "potentially" hitting the deadline was a better-case scenario, what could be expected if a fix (the voucher) was put in place.

Bottom line: a reasonable jury could conclude that, by the end of fall 2017, the Franchise President and the Chief Operating

subsequent [Drug application]"); <u>see also</u> Cecchi Declaration, Ex. 116 CELG-AMF 00957454 (October 2016 internal presentation on Drug application: "Dec 2017 . . . filing commitment based on previous staggered timelines; current plan is heavily backloaded - Huge workload on team with little time for delays/errors").

And note: lower-level Company employees prepared an extensive talking points-type document for how they would explain the lateness of the Metabolite discovery. See Cecchi Declaration, Ex. 15 at CELG-AMF 01076636-38. Why did they feel the need to do so? One inference: it was understood that other Company employees involved in Drug development would themselves have understood how worrisome the late Metabolite discovery was, and could demand an accounting.

Officer knew that, without more runway, time was close to being too tight or was <u>already</u> too tight. As the briefing book had articulated --- long term studies take a long time; they were viewed as "central" by the FDA; 44 and without them there was a large risk that the Drug application would be rejected by the FDA because it was not "complete." <u>See</u> Plaintiffs' Letter (May 24, 2024) Exhibit D at CELG-AMF 00934606.

* * *

All of the above set the stage for the FDA's response to the Company's briefing book request to submit Metabolite studies late.

The FDA's response to the request: no. <u>See</u> Defendants' Rule 56 Statement ¶¶ 52, 54.

The Company had asked in the briefing book whether the FDA agreed "that the overall proposed clinical pharmacology package, including the additional information planned to be provided early in the NDA review, is acceptable and supports the filing for the registration of [the Drug]?" Cecchi Declaration, Ex. 42 at CELG-AMF 01421087.

The FDA's response:

No. A complete clinical pharmacology package, including all relevant . . . studies and population . . . analyses is required at the time of submission . . . You propose to submit an abbreviated clinical study report (CSR) of study RPC01-1001 at the time of NDA submission. Full CSRs (including the bioanalytical and validation reports) for this study and all relevant clinical . . . studies are needed at the time of the NDA submission.

Id. (emphasis added).

The Company had also asked in the briefing book:

Question 5: Does the Agency agree with Celgene's proposed timing for the bioanalytical data package for the recently-identified major and active [M]etabolite . . . ?

Id. at CELG-AMF 01421088.

The FDA:

Include the Validation and Analytical Study Reports for all major metabolites in the CSRs . . . These reports $\underline{\text{must}}$ be available at the time of the NDA submission . . . If

See Plaintiffs' Letter (May 24, 2024), Exhibit D at CELG-AMF 00934606.

you used retained plasma samples to quantify [the Metabolite] in the relevant Phase 1 studies, you will need to provide evidence that demonstrates the stability of [the Metabolite] in human plasma at the time of the NDA submission.

Id. (emphasis added).

On the day after the FDA's response came in, the Franchise President received it. <u>Compare</u> Yadava Declaration, Ex. 51 at CELG-AMF 01024007 (November 21, 2017 email from the FDA to the Company containing the feedback) <u>with Cecchi Declaration</u>, Ex. 127 at CELG-AMF 04643283-84 (FDA feedback being sent on November 22, 2017 to the Franchise President). And the Chief Operating Officer received the FDA feedback on that same day, too.⁴⁵ <u>See</u> id.

Moreover, there is no indication that the FDA later took a softer line. The Company sought clarification from the FDA about whether it could submit a particular Metabolite study a month late --- and the FDA again said no. 46

The Franchise President and the Chief Operating Officer received an email; the email plainly appears to have been conveying, or attempting to convey, the FDA response as an attachment. See Cecchi Declaration, Ex. 127 at CELG-AMF 04643284 ("Please see the feedback received from FDA in response to the Briefing Document submitted for the Pre-NDA Meeting scheduled for November 27th"). The Chief Operating Officer responded to the email chain. See id. at CELG-AMF 04643283. The Franchise President did, too. See id. (Franchise President: "I will reply tomorrow once I have reviewed the FDA feedback."). But the email chain as put into evidence here does not actually include the FDA-response attachment. The Plaintiffs, though, are entitled to the inference that it was attached. generally Dejewski, 2024 WL 2744981, at *5 n.11. Given the importance of the issue, and the focus on it --- it is reasonable to infer that if an email that sought to attach the FDA's response did not in fact do so, the Chief Operating Officer and the Franchise President would have followed up, to put hands on it. And the inference that the Chief Operating Officer and the Franchise President were aware of the FDA feedback is strengthened by what was to come (of which more in a moment).

The Company posed the following question to the FDA on November 22, 2017. "Request for Clarification: [the Company] is requesting to submit the full CSR [clinical study report] for [a certain Metabolite study] 1 month after the [Drug application]

Based on all this, a reasonable jury could conclude:

The implications of the FDA feedback for the Drug application were unmissable. Drug studies that had been projected in the briefing book to take many months, see Plaintiffs' Letter (May 24, 2024), Ex. D at CELG-AMF 00934605, were now "needed" and had to be provided ("must be submitted") when the Drug application was to be filed --- in five or six weeks. Whatever course the Company chose --- go forward without long-term studies, or try to cram and do long-term studies in the short term --- there was now a large risk that, if the Company stuck to the end-of-2017 deadline, the FDA would "refuse to file" the Drug application as incomplete.

* * *

And a reasonable jury could conclude: this was not only unmissable --- it was not missed.

Six days after the Company received the FDA's feedback, on November 27, 2017, a Franchise executive forwarded a "tracker" to several people, including the Franchise President. See Cecchi Declaration, Ex. 7 at CELG-AMF 04856772. The Franchise President forwarded it to the Chief Operating Officer, 47 and said she would "update" him "in person" as to the FDA feedback. See Cecchi Declaration, Ex. 6 at CELG-AMF 04619727.

The tracker was a summary document, designed to help Company employees follow ("track") information on the Drug by providing an easy-to-digest table. See Cecchi Declaration, Ex. 7 at CELG-AMF_04856773-780. Two of the entries in the table pertained to the Company's now-rejected proposal to make a late submission as

submission . . . Does the Agency agree?" The FDA responded: "We do not agree . . . applications are expected to be complete at the time of original submission of the application . . . [the referenced Metabolite study] is a major component of your application." Yadava Declaration, Ex. 53 at CELG-AMF 01030233.

The "tracker" is not in the same exhibit as the email to the Chief Operating Officer. See Cecchi Declaration, Ex. 6.

Instead, the Plaintiffs point to the "tracker" that is in the next exhibit, Exhibit 7. See Plaintiffs' Rule 56 Statement ¶ 67. And they represent that the "tracker" in the next exhibit was the one emailed to the Chief Operating Officer. See id.

The Defendants do not contest this, and with good reason.

Numerous context clues, plus shared file names ("Ozanimod RMS NDA MAA Tracker.docx."), make a strong case that the Plaintiffs have it right, and a reasonable jury could easily conclude they do.

to Metabolite-related tests. These were listed as presenting "refusal to file" issues. <u>Id</u>. at CELG-AMF 04856776, 79 (emphasis added).

There are, to be sure, competing inferences that can be drawn from these invocations of a "refusal to file" outcome.

But a reasonable jury could opt to infer that theses references made the Franchise President and the Chief Operating Officer directly and explicitly aware of a large risk that a "refusal to file" was right around the bend --- that even hurriedly pulled-together Metabolite studies would not do the trick, and that a Drug application submitted at the end of 2017 would be promptly sent back by the FDA as incomplete.

* * *

The dissonance between (a) this apprehension of a large risk and (b) Company statements 8, 9, and 10 (which spoke about FDA consideration of the Drug application but said nothing about any risk), could lead a reasonable jury to conclude that the Franchise President and the Chief Operating Officer had scienter as to these statements.⁴⁸

And such a jury conclusion would not be erroneous as a matter of See Glazer Cap. Mgmt., L.P. v. Forescout Techs., Inc., 63 F.4th 747, 779-80 (9th Cir. 2023) (scienter sufficiently alleged where defendants touted that an expected merger would occur on time, though they knew there were specific concerns with one party's ability to satisfy closing conditions); Zak v. Chelsea Therapeutics Int'l, Ltd., 780 F.3d 597, 603, 609-11 (4th Cir. 2015) (scienter sufficiently alleged where drug company touted that it had submitted a drug application based on "robust" data, but knew and did not disclose that the FDA had given feedback recommending that it submit additional data that the company did not have); Lormand v. US Unwired, Inc., 565 F.3d 228, 232-36, 250-54 (5th Cir. 2009) (scienter sufficiently alleged where company made generally positive public representations about a critical partnership with another company, despite "known risks" to the partnership that would have been severely financially damaging if they came to pass); Miss. Pub. Emps. Ret. Sys. v. Bos. Sci. Corp., 523 F.3d 75, 87-91 (1st Cir. 2008) (scienter sufficiently alleged where defendants had publicly attributed a product problem to a cause that would be easily resolvable --but did not disclose a known risk that the problem might actually be a defect that could require a recall, where there

As before: the Court proceeds on the assumption that the Franchise President and the Chief Operating Officer were aware of the statements. See Part V.A.2.

were allegations that the company made contingency plans to prepare for the potential recall); Pirraglia v. Novell, Inc., 339 F.3d 1182, 1191-92 (10th Cir. 2003) (scienter sufficiently alleged where executives made statements that included revenue from certain transactions, but, among other factors, were aware of risks that the party on the other side was not creditworthy); cf. S. Ferry LP, No. 2 v. Killinger, 542 F.3d 776, 782-84 (9th Cir. 2008) (a company's knowledge of its lack of capacity in a certain area, which created a risk to its performance in a touted area of strength, was evidence of scienter).

VI. Conclusion

The Court has reached three conclusions in Parts IV and V.

First, a reasonable jury could not determine that the Chief Operating Officer (Smith) had scienter for statements 1 to 7, or that the Franchise President (Curran) had scienter for statements 1 to $4.^{49}$ See Part V.E.1.a. Accordingly, there is no basis (indicated by an X mark) for imputing scienter to the Company from these people for these statements.

<u>Second</u>, further information is needed to determine whether a reasonable jury could conclude that the Franchise President had scienter as to statements 5 to 7. See Part V.E.1.b.

And third, a reasonable jury could conclude that the Chief Operating Officer (Smith) had scienter for Statements 8 to 10, see Part V.E.2, and that the Franchise President did, too, see id. Accordingly, there is a potential basis (indicated by a check mark) for imputing scienter to the Company from these people for these statements.

Whether imputing such scienter to the Company makes sense here is the subject of the next Part.

For now, a summary of the Court's Part IV and Part V conclusions: 50

⁴⁹ As to statements 1 through 7 and the Chief Operating Officer, Judge Vazquez reached the same conclusion and that is law of the case. <u>See</u> Part IV.A. As to statements 1 through 4 and the Franchise President, this conclusion is consistent with the "rule of law" laid down by Judge Vazquez in his decision as to the Chief Operating Officer. See Part IV.B.

[&]quot;FI" in the chart stands for the further information that is needed.

Statement	When	Smith	Curran	Martin ⁵¹
1	July 27, 2017	X	X	
2	July 27, 2017	X	X	
3	July 27, 2017	X	Х	
4	September 26, 2017	X	Х	
5	October 26, 2017	X	FΊ	
6	October 26, 2017	X	FI	
7	October 26, 2017	Х	FI	
8	January 8, 2018	٧	√	
9	January 25, 2018	√	V	
10	February 7, 2018	√	V	

VII. Imputation of Scienter to the Company

Take up now, in three parts, the question of whether the scienter of the three individuals that have been discussed can be charged to the Company.

First, the Court introduces the relevant legal issues. <u>See</u> Part VII.A.

Next, the Court sets out the controlling law. See Part VII.B.

And finally, the Court applies the law and reaches two conclusions. First, the scienter of the Franchise President and the Chief Operating Officer can be imputed to the Company. See Part VII.C.1 and VII.C.2. And second, the Managing Director did not have scienter --- and even if he did, it could not be imputed to the Company. See Part VII.C.3.

A. Introduction

The stepping-off point here is a question --- when can an employee's knowledge count as its employer's knowledge? --- that comes up in various corners of the law. 52

There has been no analysis to this point as to the Managing Director (Martin), for reasons that are taken up in Part VII.

For some criminal law examples, see New York Cent. & H.R.R.

Co. v. United States, 212 U.S. 481, 495 (1909), United States v.

Philip Morris USA Inc., 566 F.3d 1095, 1118 (D.C. Cir. 2009),

But this question has been asked somewhat infrequently in cases under the Exchange Act of 1934. Relatively few cases explain the circumstances under which an employer (here, a corporation) can be liable under 10b-5 based on the knowledge ("scienter") of one or more of its employees. Cf. Donald C. Langevoort, Lies Without Liars? Janus Capital And Conservative Securities

Jurisprudence, 90 Wash. U. L. Rev. 933, 959 (2013) (describing "corporate scienter" as "one of the greatly under-theorized subjects in all of securities litigation"); Daniel McLaughlin & Mark Taticchi, Corporate Scienter Under Section 10(b) and Rule 10b-5, Bloomberg BNA Sec. Regul. & L. Rep. at 1 (similar).

How to begin tackling this question is not crystal clear.

Nearly all federal courts that have considered whether scienter under 10b-5 can run to a corporation from a person have implicitly assumed that the question is controlled by federal common law --- with federal common law often (though not always) understood to be rooted in the overarching general principles reflected in the common-law of agency. See, e.g., Meitav Dash Provident Funds & Pension Ltd. v. Spirit AeroSystems Holdings, Inc., 79 F.4th 1209, 1230 (10th Cir. 2023); Jackson, 960 F.3d at 99; Smallen v. The W. Union Co., 950 F.3d 1297, 1313 (10th Cir. 2020); ZPR Inv. Mgmt. Inc. v. Sec. & Exch. Comm'n, 861 F.3d 1239, 1252 (11th Cir. 2017); In re ChinaCast Educ. Corp. Sec. Litig., 809 F.3d 471, 476 (9th Cir. 2015); In re Omnicare, Inc. Sec. Litig., 769 F.3d 455, 474 (6th Cir. 2014); In re NVIDIA Corp. Sec. Litig., 768 F.3d 1046, 1063 (9th Cir. 2014); Makor Issues & Rts., Ltd., 513 F.3d at 708-09; Southland Sec. Corp. v. INSpire Ins. Sols., Inc., 365 F.3d 353, 366-67 (5th Cir. 2004); Adams v. Kinder-Morgan, Inc., 340 F.3d 1083, 1106 (10th Cir. 2003), as amended on denial of reh'g (Aug. 29, 2003); Sec. & Exch. Comm'n v. City of Victorville, 2018 WL 3201676, at *3 (C.D. Cal. Jan. 24, 2018); Patel, 2016 WL 1629325 at *15 n.38; Sec. & Exch. Comm'n v. Sells, 2012 WL 3242551, at *8-9 (N.D. Cal. Aug. 10, 2012).53

United States v. Brown, 763 F.2d 984, 993 (8th Cir. 1985), and
United States v. George F. Fish, Inc., 154 F.2d 798, 801 (2d
Cir. 1946). For some civil law examples, see Am. Soc. of Mech.
Eng'rs., Inc. v. Hydrolevel Corp., 456 U.S. 556, 568 (1982), Am.
Tel. & Tel. Co. v. Winback & Conserve Program, Inc., 42 F.3d
1421, 1431, 1434-41 (3d Cir. 1994), and United States ex rel.
Vavra v. Kellogg Brown & Root, Inc., 727 F.3d 343, 348 (5th Cir. 2013).

Two points here. <u>First</u>, the turn to agency principles is likely based on the idea that "Congress is understood to

legislate against a background of common-law adjudicatory principles." Astoria Fed. Sav. & Loan Ass'n v. Solimino, 501 U.S. 104, 108 (1991); see also Duvall v. Atty. Gen. of U.S., 436 F.3d 382, 387 (3d Cir. 2006); Doyle v. Matrix Warranty Sols., Inc., 679 F. Supp. 3d 42, 45 (D.N.J. 2023). Long before the passage of the Exchange Act of 1934, the relevant "background . . . principles" have included a menu of doctrines used to determine when an agent's knowledge might run upstream, and count as the principal's. See McIntire v. Pryor, 173 U.S. 38, 52-53 (1899) (discussing such knowledge imputation); Am. Sur. Co. of New York v. Pauly, 170 U.S. 133, 156-160 (1898) (same); Story on Agency (1874) § 140 (same); see generally Theodore Plucknett, A Concise History of the Common Law 443-47 (4th ed. 1948) (describing the development from the 13th century forward of common law vicarious liability doctrines). A second point. When interpreting 10b-5, the Supreme Court has often looked to standard statutory interpretation principles. See, e.g., Janus, 564 U.S. at 142-47. When it has not done so, the Court has often (though not always) analyzed securities law in a federal common law vein --- looking to general, overarching principles drawn from the common law as a whole, rather than borrowing from the law of one particular state. See, e.g., Dura Pharms., Inc. v. Broudo, 544 U.S. 336, 343-46 (2005) (using common law principles to inform interpretation of loss causation under Section 10(b)); Wharf (Holds.) Ltd. v. United Int'l Holdings, Inc., 532 U.S. 588, 596 (2001) (using common law principles to inform interpretation of implied misrepresentation under Section 10(b)); cf. Basic Inc. v. Levinson, 485 U.S. 224, 253 (1988) (White, J., concurring in part and dissenting in part) ("In general, the case law developed in this Court with respect to § 10(b) and Rule 10b-5 has been based on doctrines with which we, as judges, are familiar: common-law doctrines of fraud and deceit."). This might be rooted in a sense that the securities laws aim to lay down uniform standards for the Nation's capital markets. And so it is better to look to federal common law --- rather than to select, using choice of law analysis, the law of one state for this case and the law of another state for the next one. Cf., e.g., United States v. Kimbell Foods, Inc., 440 U.S. 715, 728 (1979) (things that "by their nature are and must be uniform in character throughout the Nation necessitate formulation of controlling federal rules") (cleaned up); Miree v. DeKalb Cnty., Ga., 433 U.S. 25, 28 (1977) ("[t]he necessity of uniformity of decision demands that federal common law, rather than state law, control").

But the Third Circuit seems to have taken a different approach. In a 2013 10b-5 case, it held that "[a]lthough the . . . underlying securities fraud claims are governed by federal law, the issue of imputation [to the corporation] is determined by state law." Belmont v. MB Inv. Partners, Inc., 708 F.3d 470, 494 (3d Cir. 2013).

* * *

Is the Third Circuit's <u>Belmont</u> decision controlling here? Given the quote, the question seems to answer itself: yes --- and state law must be applied, not federal common law.

But there may potentially be some reason to slow down.

Belmont focuses on imputation of liability, not knowledge. <u>See</u> Belmont, 708 F.3d at 494-98.

More fundamentally, the quoted language must be read in the context of the case that generated it, see, e.g., OI Eur. Grp. B.V. v. Bolivarian Republic of Venezuela, 73 F.4th 157, 175 n.22 (3d Cir. 2023) --- and the Third Circuit has in general emphasized that "the applicability of common law doctrines in litigation under federal statutes depends on whether those principles advance the goals of the particular federal statute which plaintiffs allege has been violated." Petro-Tech, Inc. v. W. Co. of N. Am., 824 F.2d 1349, 1356 (3d Cir. 1987).

Against that backdrop, an argument can at least potentially be constructed to suggest that <u>Belmont</u> is distinguishable, and does not control here --- because the case is factually far afield, and because applying state common law doctrines does not "advance" the relevant federal statutory "goal[s]." Id.

This possible argument is sketched out below.

* * *

The need to advance a "federal policy or interest" is one reason to choose a federal common law rule over a state-by-state rule.

O'Melveny & Myers v. F.D.I.C., 512 U.S. 79, 87 (1994); see also, e.g., Atherton v. F.D.I.C., 519 U.S. 213, 218 (1997); Wallis v. Pan Am. Petroleum Corp., 384 U.S. 63, 68 (1966).

Here, the "federal policy or interest" in play is ensuring the integrity of the securities-disclosure regime that Congress created. See 15 U.S.C. §§ 78m, 78o(d); see also 17 CFR §§ 249.308a, 310; see generally Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit, 547 U.S. 71, 78 (2006) ("[t]he magnitude of the federal interest in protecting the integrity and efficient

operation of the market for nationally traded securities cannot be overstated").

The securities disclosure regime was not implicated in Belmont. There were no allegations as to statements in SEC filings.

But the opposite is true here. This case is largely about asserted inaccuracies in SEC filings. 54

Cases like this one, which zero-in on alleged misrepresentations in securities disclosures, aim to compensate the injured. They also generate practical incentives for companies to get it right when it comes to their SEC filings.

But there is a balance to be struck. The background rule as to disclosures is that there is not much that needs to be said --- but that what is said needs to be accurate. See, e.g., Matrix Initiatives, Inc. v. Siracusano, 563 U.S. 27, 44-45 (2011); In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1427 (3d Cir. 1997).

In light of that rule, courts have long noted a potential difficulty. Robust private-party civil enforcement of disclosures' accuracy can help investors. But if the law widens the aperture too far, the knock-on effect may be to induce companies to make only sparse disclosures --- and that can hurt investors. One formulation of the point is Judge Friendly's:

If the only choices open to a corporation are either to remain silent and let false rumors do their work, or to make a communication, not legally required, at the risk that a slip of the pen or failure properly to amass or weigh the facts --- all judged in the bright gleam of hindsight --- will lead to large judgments, . . . most corporations would opt for the former.

Sec. & Exch. Comm'n v. Tex. Gulf Sulphur Co., 401 F.2d 833, 867 (2d Cir. 1968) (Friendly, J., concurring).

In short: the balance struck as a matter of securities law (as to how easy or how hard it is to challenge the <u>quality</u> of any disclosures made) can impact the balance companies then strike

In <u>Belmont</u>, the alleged fraud was both direct and fairly localized. <u>See Belmont</u>, 708 F.3d at 477-83. People spoke to each other and lied; those who were lied to relied on the lie. <u>See id</u>. at 479-80. Here, the alleged fraud did not involve a direct misrepresentation, from one person to another. Rather, it concerned alleged misrepresentations in public statements and filings --- misrepresentations that, per the fraud-on-the-market doctrine, were presumptively relied on by millions of shareholders. See Complaint ¶¶ 426, 473, 479-81.

in their securities filings (as to the <u>quantity</u> of disclosures they choose to make).

After the Supreme Court's decision in <u>Janus</u>, the law's balance will often be struck as a matter of knowledge-imputation law. That is the body of law that will determine whether the corporation can be liable. And in a case bottomed on an inaccurate SEC filing case, <u>Janus</u> means that the corporation may be the only defendant (or one of the only defendants). <u>Cf. In re Celgene Corp.</u>, <u>Inc. Sec. Litig.</u>, 2024 WL 3503486, at *1 (D.N.J. July 23, 2024).

If knowledge-imputation is a matter of federal common law, the referenced balance will be struck by the federal courts --- intentionally, and with an eye to protecting a key "federal . . . interest," O'Melveny & Myers, 512 U.S. at 87, the disclosure regime created by Congress, with all the trade-offs that are built into it (including the one alluded to by Judge Friendly).

If, by contrast, knowledge-imputation is treated as a matter of state law, then the picture will be different.

State common law will be brought to bear, even though it has not historically been applied in this context --- and therefore has not been shaped by the possibility that certain otherwisesensible legal rules might carry with them a distinctive downside in this context, by discouraging fulsome corporate disclosures as a practical matter.

And moreover, the state knowledge-imputation law that is brought to bear will, in the aggregate, probably tend to pull in one particular direction. Securities fraud suits can often be filed in a range of venues. And plaintiffs will presumably opt to bring their cases where state law tends to generate a particular outcome as to knowledge-imputation.

As a result of all this, the "federal policy or interest" here, id., of protecting Congress' finely-balanced disclosure regime, would be left not to federal law but to state law --- and likely to the law of those states that would tend to lean the balance to one side. And this could well have the practical knock-on effect of trimming back on the breadth of SEC disclosures that U.S.-registered corporations choose to make.

* * *

The above is an outline of an argument that might be put forward --- as to why <u>Belmont</u> might be distinguishable, and a federal common law of knowledge-imputation should be applied in cases like this one, not a state law approach.

Is this argument persuasive? Not clear. The argument is only lightly sketched, and there are plainly strong counterarguments. The Court has no present view on whether the argument would or would not hold up in the end.

Why then bring it up? To demonstrate that, even given $\underline{\text{Belmont}}$, it is at least possible that $\underline{\text{either}}$ state law (presumably New Jersey law⁵⁵) $\underline{\text{or}}$ federal law (as informed by general agency principles) governs the knowledge-imputation question at issue here.

There is no need to definitively choose between these two possible approaches (state vs. federal) unless they pull in different directions. In some contexts, they will. But not here. In this case, the legal principle needed to resolve the knowledge-imputation question is a highly general one. See Part VII.C.

The next section, <u>see</u> Part VII.B, lays out that principle --- and shows that it does not meaningfully vary regardless of the law that is applied: New Jersey law, or the overarching agency principles that undergird any federal common law.

This means that for the purposes of this case there is no need to choose between state law and federal common law approaches to knowledge-imputation. Both point in the same direction.

B. Law

When is the knowledge of employees imputed to their employers?

The answer is a matter of agency law. And one of agency's bedrock principles is that liability can typically be imputed to an employer for the acts of an employee --- provided the employee was acting within the scope of that employee's duties. See, Eage, Carter v. Reynolds, 175 N.J. 402, 408-10 (2003); Lehmann v. Toys R Us, Inc., 132 N.J. 587, 619 (1993); Lane v. City of Juneau, 421 P.3d 83, 94-95 (Alaska 2018); Michelson v. Exxon Rsch. & Eng'g Co., 808 F.2d 1005, 1007-08 (3d Cir. 1987) (applying Pennsylvania law); Restatement (Second) of Agency § 219 (1958).

When it comes to imputing knowledge from an employee to an employer, the general principle is somewhat similar.

Namely: knowledge can typically be imputed to an employer if (a) the employee gained or used the knowledge in connection with the

The Court entered an order directing the parties to consider the impact of <u>Belmont</u>. The parties filed letter briefs. But no one made a choice of law argument or otherwise suggested that a state law other than forum law (New Jersey law) might apply.

task the employee was assigned, or (b) the knowledge was tightly connected to the employee's assigned task. 56

That principle is what the cases summarized in this Part generally add up to.

* * *

Start with two New Jersey Supreme Court cases.

First, <u>Handleman</u> v. <u>Cox</u>, 39 N.J. 95, 104 (1963).

There, a silverware salesperson visited a diner. See Handleman, 39 N.J. at 100. A diner employee, planning on buying some silverware for the diner, asked the salesperson to bring the silverware around back, to the entrance to the diner's kitchen. See id. The salesperson walked around the building, and came to a doorway. See id.

There was a raised platform near the doorway, with a stairwell next to it. See id. But the salesperson could not see the stairs --- a coffee carton was on the platform, blocking the view. See id. at 101. The salesperson fell down the steps, got hurt, and sued the owners of the diner. See id. at 98, 101.

Liability for the diner owners came down, in part, to whether they had knowledge of the coffee carton's location, and thus were negligent. See id. at 102-04.

The owners themselves did not know about the carton. And the carton was not actually placed there by an employee of the diner, but rather by a delivery person. See id. at 101.

But one of the diner's employees knew about the carton. <u>See id</u>. at 102. Could that knowledge be imputed to the diner owners?

The New Jersey Supreme Court's answer: yes. <u>See id</u>. at 105. The reasoning: though the employee had not created the dangerous

Two things. First, it appears that courts have tended to treat employee duties/tasks in a more capacious way for the purpose of imputing liability than for the purpose of imputing knowledge. The different verbal formulations used in the text --- "scope of duties" versus "the task that the employee was assigned" are an effort to allude to that seeming distinction.

Second, the Court's formulation is necessarily inexact --- it is an effort to provide a shorthand description of many cases, and so there are any number of wrinkles it does not seek to account for. But the formulation captures the law's main lines, to the extent relevant here. And there are fuller formulations later in this section, quoted from the Restatement and other sources.

condition, he knew of it. <u>See id</u>. And that knowledge was chargeable to the owners not just because he worked for them⁵⁷ -- but because keeping an eye out for cartons and the like was a specific part of the task that the employer had set out for the employee. Per the Supreme Court: the jury could infer the employee was "responsible for putting food supply and merchandise deliveries in their proper places, or at least not permitting cartons to remain in a position which might cause danger to others lawfully on the premises." <u>Id</u>. at 104; <u>id</u>. ("a principal is charged with the knowledge of his agent . . respecting matters lying within the scope of the duties, activities, and responsibilities entrusted to him by the principal").

For a <u>second</u> case, look to a more recent New Jersey Supreme Court <u>decision</u>: <u>Pfenninger</u> v. <u>Hunterdon Cent. Reg'l High Sch.</u>, 167 N.J. 230 (2001).

There, a contractor agreed to install a drainage system for a school's sports fields. See Pfenninger, 167 N.J. at 237.

The school board was required to provide the materials for the drainage system. See id. at 238. The plans called for a specific sort of pipe, which could be installed without him having to enter the trench that was being dug. See id. But the school board was sent the wrong sort of pipe, which seemingly could not be installed in the same way. See id. at 238-39. Then, "[u]nder pressure from the [school board, . . . the contractor] decided to use the nonconforming pipe and entered the trench to connect the sections of pipe." Id. at 239. The trench collapsed, and the contractor was killed. See id. at 234, 240.

The contractor's widow sued the school board. <u>See id</u>. at 234. Liability came down, in part, to whether the board knew that the sort of pipe that was used was relatively more dangerous. <u>See id</u>. at 242.

There was no evidence the board itself knew. See \underline{id} . at 241. But the project's architect did. See \underline{id} . at 242.

The New Jersey Supreme Court held that the architect's knowledge that the first pipe was safer could be imputed to the school board, because (1) he was an agent of the board, (2) he was

The Plaintiffs in this case argue that "[u]nder New Jersey law, a principal is deemed to know facts that are known to its agent." Plaintiffs' Letter (May 24, 2024) at 1 (cleaned up). This is much too expansive a view of the law, as shown throughout Part VII.B.

"presid[ing]" over the Board's project to renovate the athletic field on behalf of the board, <u>see id</u>. at 242, and (3) the project was "within the scope of the duties, activities, and responsibilities entrusted to him by the principal." <u>Id</u>. at 242 (quoting Handleman, 39 N.J. at 104).

Same point as before: knowledge was imputed to an employer because it had been gained by the employee/agent in the course of doing the task assigned by the employer --- the task the agent had been "entrusted" with, the construction project he "presided" over. 58

* * *

New Jersey's approach is no outlier.

To see the point, look first to some typical cases from other jurisdictions.

Start with <u>Anderson</u> v. <u>General Cas. Ins. Co.</u>, 402 Md. 236 (2007). There, a business owner bought an insurance policy. The business owner used an insurance agent. See id. at 240.

The insurance company tried to cancel the policy. See id. at 241-42. To do so, it mailed a notice to the address it had on file: that of the insurance agent. See id. at 242.

For other New Jersey cases that take essentially this tack, see: Benjamin v. Corcoran, 268 N.J. Super. 517, 528 (App. Div. 1993) (employees knew that a dog was dangerous, and the employees' responsibilities included keeping the premises safe; the employees' knowledge of the danger was imputed to the entity that owned the property); Rovensky v. B&W Ltd. Holdings, LLC, 2012 WL 1987109, at *1 (N.J. Super. Ct. App. Div. June 5, 2012) (similar); Colegrove v. Behrle, 63 N.J. Super. 356, 365 (App. Div. 1960) (land purchasers hired a set of lawyers to work on a land deal on their behalf; in working on the transaction, the lawyers gained knowledge of a certain claim of title, and that knowledge was imputed to the land purchasers). For cases that are a bit less on-point, but still consistent, see: Heake v. Atl. Cas. Ins. Co., 15 N.J. 475, 478-85 (1954) (insurance agent, selling a customer a policy on behalf of an insurance company, sold a policy to a customer that he knew would not serve the customer's needs; his knowledge was then imputed to the insurance company); Panchak v. Simmons Co., 15 N.J. 13, 19 (1954) (workers compensation lawsuit; a supervisor of a certain employee learned about the employee's injury in the course of supervising that employee, and thus the supervisor's notice of the injury could be imputed to employer).

An accident occurred, a claim was filed, and the insurance company declined to pay --- because the policy had been cancelled. See id. The business owner sued, alleging the cancellation was improper --- the agent was mailed the cancellation, but the business owner did not know about it. See id.

The Maryland Court of Appeals held that the agent's knowledge of the policy-cancellation could be imputed to the business owner, because of the role the business owner had assigned him. "Where the matter is one that falls within the agent's scope of authority, the principal is charged with that knowledge. . . . Because [the business owner] intended to appoint [the insurance agent] as his agent for purposes of procuring insurance and receiving related notices, and [the agent] did actually receive notice within the scope of that agency." Id. at 248.

Take another case, Roberts v. William N. & Kate B. Reynolds Mem'l Park, 281 N.C. 48 (1972).

A golfer rented a golf cart. See id. at 50. The golfer drove up a steep hill to play a shot. See id. at 51. When he stopped, the cart rolled backward and kept going, despite the golfer repeatedly hitting the brakes. See id. at 51-52. The cart crashed, and the golfer was hurt. See id. at 52.

The golfer sued the company that rented him the cart. <u>See id</u> at 53-54. Liability for the company came down, in part, to whether it knew about the brake defect. See id.

The company did not know about it. But an employee of the company did. See \underline{id} . at 55. The question was whether knowledge could be imputed to the company. See \underline{id} . at 60.

The North Carolina Supreme Court's answer: knowledge could be imputed. See id. at 60. Maintenance of golf carts was under the supervision of the referenced employee. See id. And his knowledge of the brake defect was "received while the agent [was] acting as such within the scope of his authority and in reference to which his authority extends." Id.

* * *

Some more examples now, from a case and from the Restatement --- as to instances in which an employee's knowledge is not charged to the employer.

Start with Great Am. Indem. Co. v. First Nat. Bank, 100 F.2d 763 (10th Cir. 1938). A bank was sued, and liability turned on whether a bank employee's knowledge (he was a cashier, who knew

of certain funds' fraudulent origin) could be imputed to the bank.

Answer: no. Knowledge could only be imputed where an employee was "acting within the scope of his authority and in reference to a matter over which his authority extends." Id. at 765. And the employee was not doing that --- rather than simply acting as a bank cashier, he was helping to change and pay off loans which were "handled in a separate and distinct department of the bank respecting which he had no authority." Id. at 766.

And another example, this one drawn from illustrations laid out in the Restatement (Third) of Agency.

A company used chemicals in a manufacturing process. See Restatement (Third) Of Agency § 5.03 (2006) at Illustration 6. And a regulation required the chemicals to be disposed of in a way that is safe for the natural environment. See id. One of the company's employees, an engineer, was responsible for monitoring the company's facilities to make sure they complied with those environmental regulations. See id. While taking an off-duty hike at the company facilities, the engineer saw that a chemical was leaking from a pipe into the ground, close to a nearby stream. See id.

In that case, the engineer's knowledge of the leaky pipe would be imputed to the company: the employee was responsible for environmental compliance. See \underline{id} .

And now a variant. Same company, but now imagine that it was a clerk in the accounts-payable department who spotted the leaky pipe --- again, while on a weekend hike on the company's grounds. See id. at Illustration 7. None of the clerk's duties related to compliance with environmental regulations. See id. The knowledge the clerk gained about the pipe did not relate to his assigned work tasks. And so, per the Restatement: the clerk's knowledge of the leaky pipe would not be imputed to the company. See id.

All of this is consistent with how American courts have generally treated the question of knowledge-imputation. 59

⁵⁹ Some more cases: <u>Duplex Envelope Co. v. Denominational</u>
Envelope Co., 80 F.2d 179, 182 (4th Cir. 1935) (an employee had knowledge of patent infringements on products sold by his employer, but learned about the infringement while working for a separate company, and did not have authority over the relevant sale of infringing products; therefore, knowledge not imputed);

In general, an employer "[i]s not bound by the knowledge of an agent who had no authority to act with reference to the matter involved," Restatement (Second) of Agency § 272 (1958) (collecting numerous cases), and "[t]he imputation of the agent's knowledge or notice to the principal within the scope of the agency or authority of the agent, is generally subject to a requirement of materiality in relation to the agent's duties, or relevance or relation to matters within the agent's authority or the agency's purpose." 3 Am. Jur. 2d Agency § 226 (2024). As Justice Story put it, in his Commentaries on the Law of Agency, "notice of facts to an agent is constructive notice thereof to the principal himself, where it arises from, or is at the time connected with, the subject-matter of his agency." Story on Agency (1874) § 140.

C. The Individuals

A quick summary of how things have stacked up so far.

First, on the assumption he was aware of the relevant statements, see Part V.A.2, the Court concluded that a reasonable jury could find that the Chief Operating Officer had scienter for the Company's statements 8 to 10. See Part V.E.2.

Nat'l Carbon Co. v. Bankers' Mortg. Co. of Topeka, Kan., 77 F.2d 614, 617 (10th Cir. 1935) (employee of a property owner learned that a tenant was planning on moving out and breaking a lease, but the employee did not have job responsibilities related to renegotiating leases, so his notice that the tenant was going to break the lease was not imputed to the property owner); Roadside Rest, Inc. v. Lankershim Est., 76 Cal. App. 2d 525, 526, 534 (1946) (similar; agent of a property owner knew a tenant was behaving in a way that potentially altered the rental agreement, but did not have job responsibilities related to altering leases, so his notice was not imputed to the property owner); Crumpton v. New York Life Ins. Co., 27 Ala. App. 137, 138 (Ala. Ct. App. 1936) (insurance agent's knowledge of potential fraud by a customer was not imputed to the insurer, because the agent learned the information in a role --- purely collecting premiums and selling insurance --- in which he had no authority to waive the company's right to make a claim for fraud). For some more cases, see, for example: Pryor, 173 U.S. at 52-53; Chief Operating Officer v. City of Council Bluffs, 264 N.W.2d 784, 790-91 (Iowa 1978); Newco Land Co. v. Martin, 358 Mo. 99, 110 (1948); Hughes v. Riggs Bank, 29 Ariz. 44, 47-50 (1925). for a broad collection of cases, see Restatement (Second) of Agency § 272 (1958).

Second, on the assumption she was aware of the relevant statements, see Part V.A.2, the Court (a) determined that a reasonable jury could find the Franchise President had scienter for the Company's statements 8 to 10, see Part V.E.2, and (b) did not yet reach a conclusion as to statements 5 to 7, see Part V.E.1.

Are these assumptions right?

And if so: can the Chief Operating Officer's scienter and the Franchise President's scienter be imputed to the Company?

Those two questions, plus an analysis of scienter and imputation as to the Managing Director, are covered just below.

1. The Chief Operating Officer

Could a reasonable jury conclude that the Chief Operating Officer was aware of statements 8, 9, and 10?

The Court's conclusion: yes. 60

The Company, like many large entities, relied on a disclosure committee to vet SEC filings and associated public communications. And, per the Chief Operating Officer, he had a role on the committee. The Chief Operating Officer testified that draft SEC filings "came to [him] for review after the franchise presidents had reviewed [the filings.]" Cecchi Declaration, Ex. 1, 39:8-16. If the Chief Operating Officer "had any comments," he could provide input or raise any issues he had. See id. at 39:18-40:14; see also id. 37:10-39:22.

Given this, the Plaintiffs are entitled to the inference that the Chief Operating Officer was aware of statement 9 (a January 25, 2018 SEC filing, an 8-K) and statement 10 (another SEC filing: a February 2018 10-K).

As to statement 8, an earnings-focused press release dated January 8, 2018, the record is not crystal clear. But the Plaintiffs are entitled to the inference that the Chief Operating Officer was aware of the release. Compare Cecchi Declaration, Ex. 1, Deposition of Scott Smith at 25:22-26:15, 27:13-31:8, 37:10-40:14 (describing the Chief Operating Officer's personal role in reviewing materials that passed through the Company's disclosure review process) with id. at 33:15-21 ("Q: And the earnings press release that accompanied the earnings call . . . , was that earnings press release also

The evidence here, and throughout, is construed as it must be --- giving all reasonable inferences to the non-moving Plaintiffs. See Canada, 49 F.4th at 345.

something that would be reviewed and finalized during the disclosure preparation process that you discussed earlier? A: Yes.").

What this adds up to: a reasonable jury could conclude that the Chief Operating Officer had scienter as to statements 8, 9, and 10. A reasonable jury could conclude there would have been a mental dissonance for anyone who (a) knew what the Chief Operating Officer did (as described in Part V.E.2) and (b) was aware of Company statements 8 through 10 (as described just above) --- and from that dissonance, a reasonable jury could infer an "intent to deceive." Ernst & Ernst, 425 U.S. at 193.

* * *

Can the Chief Operating Officer's scienter be imputed to the Company? Yes.

Knowledge can typically be imputed to an employer if the employee gained the knowledge by performing a task assigned by the employer. See Part VII.B.

The Chief Operating Officer was plainly assigned to serve on the Company's disclosure-review committee. And it was from serving on that committee, a jury could find, that the Chief Operating Officer learned of what was in the SEC filings and in the press release --- and that awareness, mixed with what the Chief Operating Officer otherwise knew, is the basis of his scienter.

The Court's conclusion on this point is closely consistent with the developing caselaw in this area.

In <u>Sells</u>, 2012 WL 3242551, a company (Hansen) made allegedly misleading statements. <u>See id</u>. at *1-5. The SEC brought an enforcement action, and the court concluded that the case could go forward because a Hansen officer who himself had scienter "was a member of Hansen's disclosure committee, which reviewed and provided comments on Hansen's press releases and SEC quarterly filings, including Hansen's annual forms that included its financial statements." <u>Id</u>. at *1. The misstatements were allegedly made in those sorts of filings. <u>See id</u>. at *1-4. And so the officer's scienter could be imputed to Hansen. <u>See id</u>. at *8.

To similar effect is Sec. & Exch. Comm'n v. City of Victorville, 2018 WL 3201676 (C.D. Cal. Jan. 24, 2018). There, an airport authority made allegedly misleading statements. See id. at *1-2. The employee of the authority who potentially had scienter did not make the statements, but was involved in crafting them. See id. at *2-3. The court concluded the case could go forward because the employee was involved with preparation, review, or approval of the authority's statements. See id. at *3. And as

such, the court held, the employee's scienter could be imputed to the airport authority. See id. at *5.61

2. The Franchise President

Come now to the Franchise President.

Waa she aware of statements 8, 9, and 10?

Statements 9 and 10 were contained in SEC filings. And the Plaintiffs are entitled to the inference that the Franchise President was aware of Franchise-related portions of these SEC filings. The basis for such an inference is the Chief Operating Officer's testimony as to the Company's disclosure review process. See, e.g., Cecchi Declaration, Ex. 1 at 39:8-16 (noting that, on the disclosure review committee, SEC filings "came to [the Chief Operating Officer] for review after the franchise presidents had reviewed"); id. at 39:24-40:1 ("Once the franchise presidents had [reviewed the relevant filing], [it] went out, and the process was that it was going to be final in a day or two."); see also id. at 38:6-22 (when the Chief Operating Officer was President of the Franchise, his "involvement [with SEC filings] would have been reviewing any relevant sections and providing comments").62

As to statement 8, the January 8, 2018 press release, the record is not as sharply-defined as it might be. But the Chief Operating Officer testified that such press releases would be "reviewed . . . during [the] disclosure preparation process," Cecchi Declaration, Ex. 1 at 33:15-21, that he had previously described --- and as noted just above, the Franchise President

⁶¹ Cf. Jackson, 960 F.3d at 99 (there must be "connective tissue" between the employees with knowledge and the misstatements); Makor, 513 F.3d at 707-12 (case could go forward because there were sufficient allegations of scienter at the corporate level where the relevant statements were "approved"); Adams v. Kinder-Morgan, Inc., 340 F.3d 1083, 1106 (10th Cir. 2003) ("The scienter of the senior controlling officers of a corporation may be attributed to the corporation itself to establish liability as a primary violator of § 10(b) and Rule 10b-5 when those senior officials were acting within the scope of their apparent authority."), as amended on denial of reh'g (Aug. 29, 2003).

Franchise-relevant sections of the SEC filings would have included materials as to the Drug, which the Franchise (and the Franchise President) were responsible for. See Part V.D.1; see also, e.g., Defendants' Rule 56 Statement $\P\P$ 4, 6.

had a reviewing role as part of that process as to Franchise matters, like the Drug. Giving the Plaintiffs the benefit of all reasonable inferences, see Canada, 49 F.4th at 345, there is just enough to conclude that a reasonable jury could find that the Franchise President was aware of the statement 8 press release.

For reasons discussed just above in connection with the Chief Operating Officer, <u>see</u> Part VII.C.2, the Franchise President's awareness of statements 8 through 10 means that she had scienter as to those --- and that scienter can be imputed to the Company.

As to statements 5, 6, and 7: what has been said above covers statement 5 (an SEC filing) and statement 7 (a press release). And statement 6 was made in slides for an earnings call; the slides were presented by the Franchise President. See Defendants' Rule 56 Statement \P 44. The Plaintiffs, in short, are entitled to the inference that the Franchise President was aware of these three statements, 5 through 7.

What that means: if a reasonable jury could conclude the Franchise President had scienter as to these three statements (a question the Court has not yet resolved, <u>see</u> Part V.E.1.b), then for reasons discussed in Part VII.C.2, that scienter can be imputed to the Company.

3. The Managing Director

Finally, consider the Managing Director.

The evidence put before the Court in connection with the Defendants' summary judgment motion is sprawling --- well over 5,000 pages' worth. The Court has scoured it, but has located no evidence that suggests the Managing Director was aware of the ten public statements that are at issue here. There is no proof that he read or spoke about the ten statements, or even heard of them. Nor is there any basis for <u>inferring</u> that he was aware of these statements --- no proof of an expectation, for example, that Company employees of a certain level were to take a look at draft SEC filings or press releases.

In their briefing, the Plaintiffs do not argue (but see footnote 65 below) that a person can have an "intent to . . . deceive," Ernst & Ernst, 425 U.S. at 193, as to a public statement they do not know exists.

Such an argument would make little sense in terms of the Plaintiffs' basic scienter theory here --- which is premised on a disjunct between a person's knowledge and a public statement they are aware of. See Part V.A.1 and V.A.2.

And such an argument would miss the mark as a legal matter.

The Supreme Court has held that scienter is "intentional or willful conduct designed to deceive or defraud investors[.]"

Dirks v. Sec. & Exch. Comm'n., 463 U.S. 646, 663 n.23 (1983);
accord, e.g., City of Dearborn Heights Act 345 Police & Fire

Ret. Sys. v. Waters Corp., 632 F.3d 751, 757 (1st Cir. 2011);
ECA, Loc. 134 IBEW Joint Pension Tr. of Chicago v. JP Morgan

Chase Co., 553 F.3d 187, 203 (2d Cir. 2009); Fire & Police

Pension Ass'n of Colo. v. Abiomed, Inc., 778 F.3d 228, 240 (1st

Cir. 2015); Kalnit v. Eichler, 264 F.3d 131, 141 (2d Cir. 2001).

A person's "conduct" cannot be "designed to deceive . . .

investors" if he does not have any sense that it is directed at
them. It was through public statements that investors were
allegedly deceived here --- but there is no proof the Managing
Director was aware of them.

* * *

To try to square the circle, the Plaintiffs point to evidence that the Managing Director "furnished" false information to various people that was later baked into Company public statements. See Opposition Brief at 13-14.

For example, there is evidence that the Managing Director emailed information to supervisors within the Company about the Drug, including to the Chief Operating Officer and the Franchise President. See, e.g., Cecchi Declaration, Ex. 3 at CELG-AMF 01030045-46 (July 2017 email about the discovery of the Metabolite, sent to the Franchise President and Chief Operating Officer); Ex. 123 at CELG-AMF 04619533 (April 2017 email from the Managing Director to the Franchise President); Ex. 127 at CELG-AMF 04643283 (November 2017 email from the Managing Director to the Franchise President and seemingly the Chief Operating Officer, with the FDA feedback to the briefing book).

And the Managing Director testified that "an important aspect of [his] job" was updating senior management on the Drug application, and keeping them involved in relevant decision—making. See Cecchi Declaration, Ex. 2, Deposition of Managing Director at 22:12-15. The Managing Director also served on the executive committee for the Franchise, where he kept committee members "aware of what the project teams were doing." Id. at 32:9-13. And he testified that the Franchise President would "ask questions about [the Drug] on a regular basis." Cecchi Declaration, Ex. 2 at 56:3-18. (For his part, the Chief Operating Officer testified that he generally "relied . . . on information he received about [the Drug] from [the Managing Director]." Cecchi Declaration, Ex. 148 at Response Nos. 2 and 3.)

This evidence moves the dial, but not nearly far enough. It does not suggest the Managing Director had scienter --- because it does not suggest he made his reports with any understanding that their substance might eventually end up in a public statement.

And there is no way to infer any such understanding on the Managing Director's part.

At least some of his email updates on the Drug are quite long. $\underline{\text{See}}$, $\underline{\text{e.g.}}$, Cecchi Declaration, Ex. 3, at CELG-AMF 01030045-46. But none refers to public statements, or to any sense from the Managing Director that he was providing information in relation to the preparation of such statements.

Moreover, no proof has been put before the Court to suggest that the Managing Director was aware: (a) of the timing of Company SEC filings, (b) that the Company had a disclosure committee, or (c) that the Chief Operating Officer and the Franchise President were on the committee.

And finally, there is no discernible pattern to the Managing Director's reports --- some were made near-in-time to the relevant public statements, see, e.g., Cecchi Declaration, Ex. 3 at CELG-AMF 01030045-46 (July 25, 2017 email), while others were not, see, e.g., Cecchi Declaration, Ex. 127 at CELG-AMF 04643283 (November 22, 2017 email).

In short, no reasonable jury could conclude that the Managing Director had scienter based on his "furnishing" of information that assertedly undergirded the ten relevant public statements -- because there is no evidence that suggests the Managing Director had any understanding that the information he provided would potentially form part of the basis for public statements.

The cases require at least some understanding of that sort. See, e.g., Makor, 513 F.3d at 708 (assessing a corporation's mental state for the purposes of Rule 10b-5 liability "requires looking to the state of mind of the individual corporate official or officials who make or issue the statement (or order or approve it or its making or issuance, or who furnish information or language for inclusion therein, or the like) rather than generally to the collective knowledge of all the corporation's officers and employees acquired in the course of their employment") (emphasis added) (cleaned up); Southland Sec. Corp., 365 F.3d at 366 (similar); Patel, 2016 WL 1629325, at *15 n.38 (similar).

And with good reason --- if a person shares information with a colleague or a supervisor without some sense that the information will then become public, there is ordinarily no

basis for concluding that the person intended to defraud investors. And per the Supreme Court, that is the standard here. See Dirks, 463 U.S. at 663 n.23.63

In short, there is not sufficient evidence here of the Managing Director "furnishing" information for public statements --- and that failure of proof also drags down with it any argument that what was furnished was false information.

The Managing Director, as noted, supplied a good deal of information up the chain internally. But because there is no proof that <u>any</u> of this information was aimed at the Company's ten relevant public statements, there can be no logical way to know <u>which</u> of the Managing Director's information updates might have been aimed at the public statements or ended up in them.

This, too, is fatal. Because it leaves no way to sift between false information that the Managing Director might have provided for the public statements (which could be problematic) and accurate information that he provided for the public statements (which could not).⁶⁴

Put differently, the Plaintiffs argue that the Managing Director committed a "culpable act." See Memorandum in Opposition at 15 (quoting In re Cognizant Tech. Sols. Corp. Sec. Litig., 2018 WL 3772675, at *32 (D.N.J. Aug. 8, 2018)). That "culpab[ility]" rests on an assertion --- that the Managing Director provided false information for the Company's statements. But that assertion is not grounded in the proof put forward. Information that he provided and that made its way into the statements may have been false, or it may have been true. There is no evidence-based way to know. At this stage, more is required, even of the non-movant. See Celotex Corp. v. Catrett, 477 U.S. 317, 323-24 (1986); Wiest v. Tyco Elecs. Corp., 812 F.3d 319, 328 (3d Cir. 2016); Player v. Motiva Enters., LLC, 240 F. App'x 513, 522 n.4 (3d Cir. 2007); Maltez v. N.J. Transit Rail Operations, Inc., 2024 WL 3276998, at *5 (D.N.J. July 1, 2024);

⁶³ For cases noting that the relevant intent is to deceive investors --- not other constituencies, like, say, supervisors --- see, for example: Pipefitters Local No. 636 Defined Benefit Plan v. Zale Corp., 99 Fed. App'x 345 (5th Cir. 2012); Plichta v. SunPower Corp., 790 F. Supp. 2d 1012 (N.D. Cal. 2011); Hill v. Tribune Co., 2006 WL 2861016, at *8 (N.D. Ill. Sept. 29, 2006); In re Cendant Corp. Sec. Litig., 109 F. Supp. 2d 225, 233-34 (D.N.J. 2000).

Except if <u>all</u> the information the Managing Director reported was false, and the Plaintiffs do not argue that.

Marino v. Brighton Gardens of Mountainside, 697 F. Supp. 3d 224, 230 (D.N.J. 2023).65

* * *

Bottom line: there is no evidence the Managing Director had scienter as to the ten particular Company statements that are relevant here.

And even if he did have such an "intent to deceive," Ernst & Ernst, 425 U.S. at 193 --- there would be no reason to impute that scienter to the Company.

To be imputed, knowledge must generally be gained or used by an employee in the course of the employee's assigned workplace tasks, or be tightly related to those assigned tasks. See Part VII.B.

On the Plaintiffs' theory, the relevant knowledge here (that is, scienter) flowed from a disjunct between (a) information that was known to the Managing Director and (b) the ten public statements that were made. See Part V.A.1.

But this argument cannot work as to scienter because, as noted above, there is no proof the Managing Director was aware of any of the public statements.

And this argument cannot work as a basis for knowledgeimputation, because even if the Managing Director was aware of the statements --- that awareness would not have linked up to any workplace duties that had been assigned to him.

At one point, the Plaintiffs also suggest the "culpable" act was failing to correct the Company's false public statements. See generally Memorandum in Opposition at 13-21. But this comes up short. First, no proof is put forward that the Managing Director read or became aware of the Company's SEC filings or press releases at any point. He could not be expected to correct what he did not know about. Second, the Plaintiffs point to no 10b-5 cases that suggest the existence of a duty to correct that runs to employees who do not prepare or review an erroneous document. And third, the Plaintiffs cite no legal authority for the proposition that a statement can be said to have been made with scienter if, after it is made, a person learns of the statement, concludes that it was false, and then does not seek to have the statement corrected. At a minimum, it is not obvious how a Time 2 failure-to-correct might run backwards, and become a Time 1 "intent to deceive." Ernst & Ernst, 425 U.S. at 193.

There is no evidence, for example, that the Managing Director was assigned to be on the disclosure review committee, or that he had any other work-related obligations that required him to assess, review, or even know about Company SEC filings or press releases.

The Managing Director, in short, did not gain or use knowledge of SEC filings or Company press releases in the course of his work. And his assigned workplace tasks, focused on developing drugs, were not tightly related to securities disclosures or Company press releases. See generally Part VII.B. That is presumably why there is no evidence he saw them.

To come back to an earlier point, <u>see id.</u>, the Managing Director would be like the accounts-receivable clerk who sees a leaky pipe (whose knowledge of the leak is not imputed to his employer) --- and not like the environmental engineer who sees the leaky pipe (whose knowledge is imputed). <u>See</u> Restatement (Third) Of Agency § 5.03 (2006) at Illustrations 5, 7.

In the end, the Plaintiffs did not "connect[] the [Managing Director] sufficiently with the alleged misrepresentations to make [his knowledge] imputable to the Company." Western Bank v. Addie, 4 S.L.R. 113, 118-19 (Scot. Ct. of Session 1867). There is simply no "connective tissue," Jackson, 960 F.3d at 99, between the Managing Director and the ten public statements at issue here --- and that is dispositive, as to both scienter and imputation.

VIII. Conclusion

The Defendants' summary judgment motion is denied as to statements 8, 9, and 10.

The motion is granted as to statements 1, 2, 3, and 4.

The motion is granted to the extent that the Plaintiffs seek to hold the Company liable for statements 1-7 based on the scienter of the Chief Operating Officer.

The motion is granted to the extent that the Plaintiffs seek to hold the Company liable for statements 1-4 based on the scienter of the Franchise President.

The motion is granted to the extent that the Plaintiffs seek to hold the Company liable for statements 1-10 based on the scienter of the Managing Director.

The motion is held in abeyance pending further briefing to the extent that the Plaintiffs seek to hold the Company liable for statements 5 - 7 based on the scienter of the Franchise President.

These holdings are reflected in the below chart. X indicates that the motion is granted, $\sqrt{}$ means it is denied, and "FI" stands for "further information" required. Smith is the Chief Operating Officer, Curran is the Franchise President, and Martin is the Managing Director.

Statement	When	Smith	Curran	Martin
1	July 27, 2017	Х	X	X
2	July 27, 2017	Х	Х	Х
3	July 27, 2017	Х	Х	Х
4	September 26, 2017	Х	Х	Х
5	October 26, 2017	Х	FΊ	Х
6	October 26, 2017	Х	FI	Х
7	October 26, 2017	Х	FI	Χ
8	January 8, 2018	٧	V	Χ
9	January 25, 2018	٧	V	Х
10	February 7, 2018	٧	٧	Х

It is on this 4th day of September, 2024 so ORDERED.

Michael E. Farbiarz, U.S.D.J.